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Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**Request for Reconsideration of Petition Pursuant to 37 C.F.R. §1.183**

**Requesting Waiver of Requirement of 37 C.F.R. § 1.64**

**That an Original Inventor (Kelly B. Smith) Execute New Oath or Declaration**

**When New Inventors Are Added With Assignee's Consent**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450



Dear Sir:

Applicant responds to the Decision on Petition mailed December 9, 2006, for which a shortened two month period of response was set. An automatic four month extension of time to respond, up to and including June 9, 2006 is respectfully requested. The requisite fee accompanies this Request.

Despite diligent efforts to locate the nonsigning inventor Kelly B. Smith, the nonsigning inventor still cannot at this time be reached or located. The last known address for Kelly B Smith is 5S486 Arlington Avenue, Naperville, Illinois 60540.

The Declaration of Daniel D. Ryan; Declaration of Judith M. Dunaway; and Declaration of Allen L. Leisten accompany this Request for Reconsideration..

The Declarations establish the following facts:

1. In late January 2006, attorney Daniel D. Ryan was informed as to a last known address and telephone number of Kelly B Smith, a former employee of Baxter Healthcare Corporation. Attorney Ryan recorded this information and planned to contact Ms. Smith and obtain her signature on the pending Declaration in a routine fashion in time to meet the response

deadline for the Petition mailed December 9, 2006. Meanwhile, he attended to other matters for his clients. (Ryan Declaration ¶¶ 2, 3)

2. As the docketed due date for responding to the Petition mailed December 9, 2006 drew near, on Thursday June 1, 2006, Attorney Ryan instructed his employee and docketing supervisor Judith Dunaway to call Kelly B Smith at the phone number 630-848-0868. and arrange to have the Declaration sent to her for signature. (Ryan Declaration ¶¶ 2, 3) (Dunaway Declaration ¶ 2)

3. Ms. Dunaway informed Attorney Ryan on June 1, 2006 that the phone number 630-848-0868 he had given her to call had been disconnected with no further information available. (Dunaway Declaration ¶ 2) (Ryan Declaration ¶ 4)

4. Attorney Ryan instructed Ms. Dunaway on June 1, 2006 to conduct internet searching for a "Kelly Smith" in the greater Chicago area, in an attempt to find her. Ms. Dunaway was able to locate a Kelly Smith in Naperville, Illinois at another phone number, but that number too had been disconnected with no further information. (Dunaway Declaration ¶ 2) (Ryan Declaration ¶ 4)

5. On Friday June 2, 2006, Attorney Ryan instructed Ms. Dunaway to prepare and deposit with the United States Postal Service the documents and correspondences addressed to Kelly B. Smith, attached as Exhibit 1 to both the Ryan and Dunaway Declarations, at the residential address 5S486 Arlington Avenue, Naperville, Illinois 60540. (Ryan Declaration ¶ 5) (Dunaway Declaration ¶ 4)

6. On Friday June 2, 2006, Attorney Ryan also contacted Allen L. Leisten, who is a private investigator retained by Attorney Ryan in the past. Attorney Ryan asked Mr. Leisten to drive to the Naperville address of Ms. Smith in an attempt to either deliver the correspondence or determine her current whereabouts. Attorney Ryan met with Mr. Leisten in Monday June 5, 2006, and gave him a copy of the correspondence that had mailed to Ms. Smith on the previous Friday. (Ryan Declaration ¶ 6)

7. On Tuesday June 6, 2006, Mr. Leister went to the address 5S486 Arlington Ave, Naperville, Illinois 60540. Mr. Leister ascertained that the house (a single family home) was empty. Mr. Leister also ascertained from a person in the neighborhood that Ms. Smith had "moved to Stroudsburg, Pennsylvania." . (Leister Declaration ¶¶ 2, 3, 4)

8. On Tuesday June 6, 2006, Mr. Leister also checked with two local Naperville post offices and was informed at each location that they were precluded by law from giving any address change for the people who resided at 5S486 Arlington Avenue. The post offices indicated that they used to provide that information but a recent law change now prevents them from giving out that information. (Leisten Declaration ¶ 5)

9. Mr. Leister went online and found that there are six (6) K. Smiths with listed phone numbers in Stroudsburg, Pennsylvania. Only one had the first name initial "K"; the others had different first names. The number for the "K Smith" in Stroudsburg, Pennsylvania was 570 402 4913. (Leisten Declaration ¶ 6)

10. Mr. Leister reported these facts to Attorney Ryan on Wednesday June 7, 2006. On June 7, 2006, Attorney Ryan instructed Ms. Dunaway to call the 570 402 4913 telephone number. Ms. Dunaway has made numerous attempts on June 7 and June 8, 2006, but has been unable to make contact with any person at that phone number. Ms. Dunaway has left a voice mail messages explaining her inquiry on an answering machine (with a prerecorded computer voice) at this phone number. No return phone call has been received to date. (Ryan Declaration ¶¶ 7,8) (Dunaway Declaration ¶ 6)

11. No information has been received to date from the U.S. Postal Service as to the status of the correspondence mailed to Kelly B Smith on June 2, 2006. These events are reflected in the accompanying Declaration of Judith M. Dunaway. (Ryan Declaration ¶ 9) (Dunaway Declaration ¶ )

The current whereabouts of Kelly B Smith remain at this date unknown, despite the diligent efforts outline above. The last known address for Kelly B Smith is 5S486 Arlington Avenue, Naperville, Illinois 60540.

The Applicant intends to continue its diligent efforts to locate Ms. Smith and obtain her signature on the Declaration, which will be forwarded to the Patent Office as soon as it is received.

Under such circumstances, as directed by MPEP 201.03 (B), applicant has submitted its Petition under 37 C.F.R. § 1.183, requesting a waiver of the requirement of 37 C.F.R. § 1.64 that Kelly B. Smith sign the new Declaration, when as here, the assignee has consented to the correction to add new inventors.

Application Serial No. 10/765,498

Request for Reconsideration of Petition to Waive Requirements

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You are authorized to charge any excess fees, or to credit overpayments, to Deposit Account No. 06-2360. A copy of this Request is attached for this purpose.

Approval of this Request for Reconsideration is respectfully solicited.

Respectfully Submitted,

By

Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.

Post Office Box 26618

Milwaukee, Wisconsin 53226

(262) 783 - 1300

Customer No.: 26308





## CERTIFICATE OF FIRST CLASS MAIL

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, with sufficient postage, on the date indicated below in an envelope addressed as follows: Mail Stop Petition, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

By:

Judith M. Dunaway

A handwritten signature in cursive script, reading "Judith M. Dunaway".

Dated: 8 June 2006

Customer No.: 26308



Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP 2 CON

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: 26 January 2004

Group Art Unit: 3761

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**DECLARATION OF DANIEL D. RYAN**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, DANIEL D. RYAN, being duly warned do hereby declare:

1. I am an attorney registered to practice before the U.S. Patent Office. My Registration Number is 29,243. I am an attorney of record in this case.

2. In late January 2006, I was contacted by phone by Alison Storaasli, who was at that time an assistant to Senior Baxter Counsel Bradford R. L. Price, Esq (Ms. Storaasli is not longer employed by Baxter). Ms. Storaasli informed me at that time that, unexpectedly, former employee Kelly B. Smith had contacted the Baxter Law Department (she had learned that Baxter was trying to get into contact with her in late 2005 to sign a Declaration), and it was learned from that unanticipated contact that Ms. Smith's address at that time was 5S486 Arlington Ave, Naperville, Illinois 60540, and that her phone number was 630-848-0868.

3. I recorded this information and planned to contact Ms. Smith and obtain her signature on the pending Declaration in a routine fashion in time to meet the response deadline for the Petition mailed December 9, 2006. Meanwhile, I attended to other matters for my clients.

4. As the docketed due date for responding to the Petition mailed December 9, 2006 drew near, on Thursday June 1, 2006, I instructed my employee and docketing supervisor Judith Dunaway to call Kelly B Smith at the phone number 630-848-0868. and arrange to have the Declaration sent to her for signature. Ms. Dunaway informed me on June 1, 2006 that the phone number 630-848-0868 I had given her to call had been disconnected with no further information available. At my instruction, Ms. Dunaway conducted internet searching for a "Kelly Smith" in the greater Chicago area, in an attempt to find her. Ms. Dunaway was able to locate a Kelly Smith in Naperville, Illinois at another phone number, but that number too had been disconnected with no further information. These events are reflected in the accompanying Declaration of Judith M. Dunaway.

5. On Friday June 2, 2006, I instructed Ms. Dunaway to prepare and deposit with the United States Postal Service the documents and correspondences addressed to Kelly B. Smith, attached as Exhibit 1, at the residential address 5S486 Arlington Avenue, Naperville, Illinois 60540. These events are reflected in the accompanying Declaration of Judith M. Dunaway.

6. On Friday June 2, 2006 I also contacted Allen L. Leisten, who is a private investigator I have retained in the past. I explained the situation to Mr. Leisten, and asked if he would drive to the Naperville address of Ms. Smith in an attempt to either deliver the correspondence or determine her current whereabouts. I met with Mr. Leisten in Monday June 5, 2006, and gave him a copy of the correspondence that we had mailed to Ms. Smith on the previous Friday.

7. Mr. Leister reported these facts to me on Wednesday June 7, 2006.:

(i) On Tuesday June 6, 2006, Mr. Leister went to the address 5S486 Arlington Ave, Naperville, Illinois 60540. Mr. Leister ascertained that the house (a single family home) was empty. Mr. Leister also ascertained from a person in the neighborhood that Ms. Smith had "moved to Stroudsburg, Pennsylvania." These events are reflected in the accompanying Declaration of Allen L. Leisten.

(ii) Mr. Leister then checked with two local post offices and was informed at each location that they were precluded by law from giving any address change for the people who resided at 5S486 Arlington Avenue. The post offices indicated that they used to provide that information but a recent law change now prevents them from giving out that information. These events are reflected in the accompanying Declaration of Allen L. Leisten.

(iii) Mr. Leister went online and found that there are six (6) K. Smiths with listed phone numbers in Stroudsburg, Pennsylvania. Only one had the first name initial "K"; the others had different first names. The number for the "K Smith" in Stroudsburg, Pennsylvania was 570 402 4913. These events are reflected in the accompanying Declaration of Allen L. Leisten.

8. On June 7, 2006, I instructed Ms. Dunaway to call the 570 402 4913 telephone number. Ms. Dunaway has made numerous attempts on June 7 and June 8, 2006, but has been unable to make contact with any person at that phone number. Ms. Dunaway has left a voice mail messages explaining her inquiry on an answering machine (with a prerecorded computer voice) at this phone number. No return phone call has been received to date. These events are reflected in the accompanying Declaration of Judith M. Dunaway.

9. No information has been received to date from the U.S. Postal Service as to the status of the correspondence mailed to Kelly B Smith on June 2, 2006. These events are reflected in the accompanying Declaration of Judith M. Dunaway.

10. The current whereabouts of Kelly B Smith remain under investigation but are at this point, despite the diligent efforts outline above, unknown.

I declare that all statements made herein of my own knowledge are true; all statements made on information and belief are believed to be true; that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC 1001, and that such willful, false statements may jeopardize the validity of the application or of this document or of any patent issuing therefrom.

Dated this 8th day of June, 2006.

By: \_\_\_\_\_

Daniel D. Ryan

# RYAN KROMHOLZ & MANION, S.C.

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Arnold J. Ericsen (Of Counsel)  
Donald Cayen (Of Counsel)

2 June 2006

Kelly B. Smith  
55486 Arlington Avenue  
Naperville, IL 60540

Re: F-5489 CIP 2 CON (USSN 10/765,498)  
Blood Processing Systems and Methods that Employ an In-Line Leukofilter Mounted in a Restraining Fixture

Dear Kelly:

We are trying to locate you to have you sign the attached Declaration.

This concerns the filing of a continuation patent application of a case on which you were named a joint inventor along with Mark Vandlik and Michael Kast. The case as originally filed (and which has issued as US Patent No. 6,709,412) was directed to the restraining fixture for the flexible leukodepletion filter. The continuation claims are more broadly directed to the concept of using a pump to direct blood through a flexible filter, and for that reason we added two new inventors, Tom Westberg and Rohit Vishnoi. I attach a copy of the application as filed, and documents signed by Tom, Rohit, Mark and Michael, as well as a consent from the assignee, Baxter to the new list of inventors.

At the time we submitted these papers, we did not know your current whereabouts. We since obtained the above address and a telephone number, but when we called the number we were told it was disconnected. We are sending these materials to the address in the hope that you are still living at this location.

Kindly sign the Declaration at the location tagged and please provide your new address (you can hand-write these in). Please initial and date the new address information.

Please call me or my assistant, Judy Dunaway, as soon as you receive these materials so we can arrange a courier to pick them up and return them to us.

Cordially,  
RYAN KROMHOLZ & MANION, S.C.

By:

Daniel D. Ryan

DDR:jd

Enclosure - As Stated

**COMBINED DECLARATION AND POWER OF ATTORNEY  
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION OR CIP)**

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type: (check one applicable item below)

- ☒ original  
☐ supplemental

Type of Application: (check one applicable item below)

- ☐ original  
☐ design

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.

- ☐ national stage of PCT

NOTE: If one of the following items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- ☐ divisional  
☒ continuation  
☐ continuation-in-part (CIP)

**INVENTORSHIP IDENTIFICATION**

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN  
IN-LINE LEUKOFILTER MOUNTED IN A RESTRAINING FIXTURE

**SPECIFICATION IDENTIFICATION**

the specification of which: (complete (a), (b) or (c))

- (a) ☐ is attached hereto.  
(b) ☒ was filed on 26 January 2004 as ☐ Serial No. 10/765 498  
or ☐ Express Mail No., as Serial No. not yet known \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

- (c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
filed on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_ (if any).

# ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

☐ In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

## PRIORITY CLAIM (35 U.S.C. § 119)

A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(d) ☒ no such applications have been filed.  
(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>

B. CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application No.	Filing Date
_____	_____
_____	_____
_____	_____

## CLAIM FOR BENEFIT OF EARLIER US and/or PCT APPLICATION(S) UNDER 35 U.S.C. § 120

☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR US PRIORITY CLAIM

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

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NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. S 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Daniel D. Ryan (29,243)  
John M. Manion (38,957)  
Laura A. Dable (46,436)  
Patricia A. Limbach (50,295)  
Thomas J. Krumenacher (56,736)

Bradford R.L. Price (29,101)  
Joseph A. Kromholz (34,204)  
Daniel R. Johnson (46,204)  
Patrick J. Fleis (55,185)  
Melissa S. Hockersmith (56,960)

(check the following item, if applicable)

- [ ] Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

---

SEND CORRESPONDENCE TO

Bradford R.L. Price, Esquire  
BAXTER HEALTHCARE CORPORATION  
Senior Counsel  
One Baxter Parkway (DF3-2E)  
Deerfield, IL 60015

DIRECT TELEPHONE CALLS TO:  
(Name and telephone number)

Bradford R.L. Price  
(847) 948-4483

---

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

MARK (GIVEN NAME) R (MIDDLE INITIAL OR NAME) VANDLIK (FAMILY (OR LAST NAME))  
 Inventor's signature *Mark Vandlik*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS HAWTHORN WOODS, IL  
 Post Office Address 7712 GENEVA DRIVE #7 OLD LAKE ROAD  
GURNEE, ILLINOIS 60031 HAWTHORN WOODS, IL 60057 *7/27/05*

Full name of second joint inventor, if any

MICHAEL (GIVEN NAME) J (MIDDLE INITIAL OR NAME) KAST (FAMILY (OR LAST NAME))  
 Inventor's signature *Michael J Kast*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) EVANSTON, ILLINOIS  
 Post Office Address 1152 ASHLAND AVENUE  
EVANSTON, ILLINOIS 60202

Full name of third joint inventor, if any

KELLY (GIVEN NAME) B (MIDDLE INITIAL OR NAME) SMITH (FAMILY (OR LAST NAME))  
 Inventor's signature *Kelly Smith*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 506 CRYSTAL PLACE  
GURNEE, ILLINOIS 60031

Full name of fourth joint inventor, if any

TOM (GIVEN NAME) WESTBERG (FAMILY (OR LAST NAME))  
 Inventor's signature *Tom Westberg*  
 Date 7/25/2005 Country of Citizenship FI  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 17820 POND RIDGE CIRCLE  
GURNEE, ILLINOIS 60031

Full name of fifth joint inventor, if any

ROHIT (GIVEN NAME) VISHNOI (FAMILY (OR LAST NAME))  
 Inventor's signature *Rohit Vishnoi*  
 Date 7/25/2005 Country of Citizenship US  
 Residence (City, State/Country) DEERFIELD, ILLINOIS  
 Post Office Address 235 WILSON AVENUE  
DEERFIELD, ILLINOIS 60015

**ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR US PRIORITY CLAIM**

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120**

I hereby claim the benefit under Title 35, United States Code, S 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, S 112, I acknowledge the duty to disclose information that is material to the examination of this application, namely, information where there is substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:**

U.S. APPLICATIONS	U.S. FILING DATE	Status (CHECK ONE)		
		Patented	Pending	Abandoned
1. 09/976,833	10/13/2001	X		
2. 09/389,504	09/03/1999			X
3. _____	_____			

**PCT APPLICATIONS DESIGNATING THE U.S.**

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NOS. ASSIGNED (if any)
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

**35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS**

**DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY APPLICATION  
CLAIMED UNDER 35 USC 119**

	Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

CHECK PROPER BOX(S) FOR ANY OF THE FOLLOWING ADD. PAGE(S) WHICH  
FORM A PART OF THIS DECLARATION

☐ Signature for sixth and subsequent joint inventors.

\* \* \*

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor.

\* \* \*

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47.

\* \* \*

☒ Added page to combined declaration and power of attorney for US Priority Claim

\* \* \*

☐ Authorization of attorney(s) to accept and follow instructions from representative

\* \* \*

*(If no further pages form a part of this declaration then end this declaration with this page and check the following item:)*

☐ This declaration ends with this page

Patent

# BLOOD PROCESSING SYSTEMS AND METHODS

## THAT EMPLOY AN IN-LINE, FLEXIBLE LEUKOFILTER

### Related Applications

This application is a continuation of co-  
5 pending United States Application Serial No. 09/976,833,  
filed October 13, 2001, and entitled Blood Separation  
Systems and Methods that Employ an In-Line Leukofilter  
Mounted in a Restraining Fixture," which is a  
continuation-in-part of United States Patent Application  
10 Serial Number 09/389,504, filed September 3, 1999, and  
entitled "Blood Separation Systems and Methods Using a  
Multiple Function Pump Station to Perform Different On-  
Line Processing Tasks," which is incorporated herein by  
reference.

### 15 Field of the Invention

This invention relates to systems and methods  
for processing and collecting blood, blood constituents,  
or other suspensions of cellular material.

### Background of the Invention

20 Today people routinely separate whole blood,  
usually by centrifugation, into its various therapeutic  
components, such as red blood cells, platelets, and  
plasma.

Conventional blood processing methods use  
25 durable centrifuge equipment in association with single

use, sterile processing systems, typically made of plastic. The operator loads the disposable systems upon the centrifuge before processing and removes them afterwards.

5                   Conventional blood centrifuges are of a size that does not permit easy transport between collection sites. Furthermore, loading and unloading operations can sometimes be time consuming and tedious.

10                   In addition, a need exists for further improved systems and methods for collecting blood components in a way that lends itself to use in high volume, on line blood collection environments, where higher yields of critically needed cellular blood components, like plasma, red blood cells, and platelets,  
15                   can be realized in reasonable short processing times.

                  The operational and performance demands upon such fluid processing systems become more complex and sophisticated, even as the demand for smaller and more portable systems intensifies. The need therefore exists  
20                   for automated blood processing controllers that can gather and generate more detailed information and control signals to aid the operator in maximizing processing and separation efficiencies.

#### Summary of the Invention

25                   The invention provides systems and methods for processing blood and blood constituents that lend themselves to portable, flexible processing platforms equipped with straightforward and accurate control functions.

30                   One aspect of the invention provides blood processing systems and methods comprising a blood processing set that includes a source of blood cells and a blood component collection flow channel coupled to the source of blood cells. The blood component collection  
35                   flow channel includes a blood cell storage container and

an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container. The in-line filter including a fibrous filter medium, first and second flexible housings, and a unitary, continuous peripheral seal. The peripheral seal is characterized by being formed by application of pressure and radio-frequency heating in a single process, to join the first and second flexible housings to each other, as well as join the fibrous filtration medium to the first and second flexible housings. The blood processing system further includes a pump station adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter.

In one embodiment, the blood processing system further includes a fixture to restrain expansion of the first and second filter housings as a result of pressure applied during operation of the pump station.

In one embodiment, the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood. Other features and advantages of the inventions are set forth in the following specification and attached drawings.

#### Brief Description of the Drawings

Fig. 1 is a perspective view of a fluid processing system that embodies features of the invention, with the doors to the centrifuge station and pump and valve station being shown open to accommodate mounting of a fluid processing set;

Fig. 2 is a perspective view of the system shown in Fig. 1, with the doors to the centrifuge station and pump and valve station being shown closed as they would be during fluid processing operations;

Fig. 3 is a schematic view of a representative

blood processing circuit formed by the fluid processing set shown in Figs. 1 and 2;

Fig. 4 is a perspective view of a blood processing chamber and associated fluid conveying umbilicus that form a part of the fluid processing set shown in Figs. 1 and 2;

Fig. 5 is an exploded top perspective view of the of a two-part molded centrifugal blood processing container, which can form a part of the fluid processing set used in association with the device shown in Figs. 1 and 2;

Fig. 6 is a bottom perspective view of the molded processing container shown in Fig. 5;

Fig. 7 is a side section view of the molded processing container shown in Fig. 5, after connection of an umbilicus;

Fig. 8 is a side section view of a three-part molded centrifugal blood processing container which can form a part of the fluid processing set used in association with the device shown in Figs. 1 and 2;

Fig. 9 is a top view of the molded processing container shown in Fig. 5, showing certain details of the separation channel;

Fig. 10 is an exploded perspective view of the centrifuge station and associated centrifuge assembly of the device shown in Figs. 1 and 2;

Fig. 11 is an enlarged exploded perspective view of the centrifuge assembly shown in Fig. 10;

Fig. 12 is a perspective view of the centrifuge assembly fully assembled and housed in the centrifuge station of the device shown in Figs. 1 and 2, with the blood processing chamber and associated umbilicus also mounted on the centrifuge assembly for use;

Fig. 13 is a perspective view of the rotor

plate that forms a part of the centrifuge assembly shown in Figs. 10 to 12, showing the latch assembly which releasably secures the processing chamber to the centrifuge assembly, the latch assembly being shown in  
5 its chamber retaining position;

Fig. 14 is a side section view of the rotor plate shown in Fig. 13, showing the components of the latching assembly as positioned when the latch assembly is in its chamber retaining position;

10 Fig. 15 is a side section view of the rotor plate shown in Fig. 13, showing the components of the latching assembly as positioned when the latch assembly is in its chamber releasing position;

15 Figs. 16 to 18 are a series of perspective view of the centrifuge station of the device shown in Figs. 1 and 2, showing the sequence of loading the processing chamber and associated umbilicus on the centrifuge assembly prior to use;

20 Figs. 19 to 22 are a series of perspective view of the centrifuge station of the device shown in Figs. 1 and 2, after loading the processing chamber and associated umbilicus on the centrifuge assembly, showing at ninety degree intervals the travel of the umbilicus to impart rotation to the processing chamber, as driven and  
25 restrained by umbilicus support members carried by the yoke;

Fig. 23 is a schematic view of a fluid processing circuit of the type shown in Fig. 3, showing certain details of the arrangement of pumps that convey  
30 blood and fluid through the circuit;

Figs. 24A and 24B are perspective views of a leukofilter that can form a part of the fluid process circuit shown in Figs. 3 and 23, the leukofilter comprising a filter media enclosed between two flexible  
35 sheets of plastic material, Fig. 24A showing the



leukofilter in an exploded view and Fig. 24B showing the leukofilter in an assembled view;

5 Figs. 25A and 25B are perspective views of the leukofilter shown in Fig. 24B in association with a fixture that retains the leukofilter during use, Fig. 25A showing the leukofilter being inserted into an opened fixture and Fig. 25B showing the leukofilter retained for use within a closed fixture;

10 Fig. 26 is a perspective view of a device of a type of shown in Figs. 1 and 2, with the lid of the device closed to also reveal the location of various components and a leukofilter holder carried on the exterior of the lid;

15 Fig. 27 is a partial perspective view of a side of the base of a device of a type shown in Figs. 1 and 2, showing a holder for supporting the leukofilter retaining fixture shown in Figs. 25A and 25B during fluid processing operations;

20 Fig. 28 is a view of one side of the leukofilter retaining fixture of a type shown in Figs. 25A and 25B, showing a mounting bracket that can be used to secure the leukofilter either to the lid-mounted receptacle shown in Fig. 26 or the base-mounted holder shown in Fig. 27; and

25 Fig. 29 is an exploded perspective view of a cassette, which can form a part of the processing set used in association with the processing device shown in Figs. 1 and 2, and the pump and valve station on the processing device, which receives the cassette for use.

30 The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall  
35 within the meaning and range of equivalency of the claims

are therefore intended to be embraced by the claims.

#### Description of the Preferred Embodiments

Fig. 1 shows a fluid processing system 10 that embodies the features of the invention. The system 10  
5 can be used for processing various fluids.

The system 10 is particularly well suited for processing whole blood and other suspensions of biological cellular materials. Accordingly, the illustrated embodiment shows the system 10 used for this  
10 purpose.

#### I. System Overview

The system 10 includes three principal components. These are: (i) a liquid and blood flow set 12 (shown schematically in Fig. 3); (ii) a blood processing device  
15 14 (see Figs. 1 and 2), which interacts with the flow set 12 to cause separation and collection of one or more blood components; and (iii) a controller 16 carried on board the device 14, which governs the interaction to perform a blood processing and collection procedure  
20 selected by the operator.

#### A. The Processing Device and Controller

The blood processing device 14 and controller 16 are intended to be durable items capable of long term use. In the illustrated and preferred embodiment, the blood  
25 processing device 14 and controller 16 are mounted inside a portable housing or case 36. The case 36 presents a compact footprint, suited for set up and operation upon a table top or other relatively small surface. The case 36 is also intended to be transported easily to a collection  
30 site.

The case 36 includes a base 38 and a hinged lid 40, which opens for use (as Fig. 1 shows). In use, the base 38 is intended to rest in a generally horizontal support surface. The lid 40 also closes for transport (see Fig.  
35 26).

The case 36 can be formed into a desired configuration, e.g., by molding. The case 36 is preferably made from a lightweight, yet durable, plastic material.

5       The controller 16 carries out process control and monitoring functions for the system 10. The controller 16 comprises a main processing unit (MPU), which can comprise, e.g., a Pentium™ type microprocessor made by Intel Corporation, although other types of conventional  
10 microprocessors can be used. The MPU can be mounted inside the lid 40 of the case 36.

Preferably, the controller 16 also includes an interactive user interface 260, which allows the operator to view and comprehend information regarding the  
15 operation of the system 10. In the illustrated embodiment, the interface 260 includes an interface screen carried in the lid 40, which displays information for viewing by the operator in alpha-numeric format and as graphical images.

20       Further details of the controller 16 can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference. Further details of the interface can be found in Lyle et al, United States Patent 5,581,687, which is also incorporated herein by  
25 reference.

As Fig. 26 shows, the lid 40 can be used to support other input/outputs to couple other external devices to the controller 16 or other components of the device 14. For example, an ethernet port 50, or an input 52 for a  
30 bar code reader or the like (for scanning information into the controller 16), or a diagnostic port 54, or a port 56 to be coupled to a pressure cuff 58 (see Fig. 3), or a system transducer calibration port 60, can all be conveniently mounted for access on exterior of the lid  
35 40, or elsewhere on the case 36 of the device 14.

### B. The Flow Set

The flow set 12 (see Fig. 3), is intended to be a sterile, single use, disposable item. Before beginning a given blood processing and collection procedure, the operator loads various components of the flow set 12 in the case 36 in association with the device 14 (as Figs. 1 and 2 show). The controller 16 implements the procedure based upon preset protocols, taking into account other input from the operator. Upon completing the procedure, the operator removes the flow set 12 from association with the device 14. The portion of the set 12 holding the collected blood component or components are removed from the case 36 and retained for storage, transfusion, or further processing. The remainder of the set 12 is removed from the case 36 and discarded.

The flow set 12 can take various forms. In the illustrated embodiment (see Figs. 1 and 3), the flow set includes a blood processing chamber 18 designed for use in association with a centrifuge. Accordingly, the processing device 14 includes a centrifuge station 20 (see Fig. 1), which receives the processing chamber 18 for use (see Fig. 12).

As Fig. 1 shows, the centrifuge station 20 comprises a compartment 21 formed in the base 38. The centrifuge station 20 includes a door 22, which opens and closes the compartment 21. The door 22 opens (as Fig. 1 shows) to allow loading of the processing chamber 18 into the compartment 21. The door 22 closes (as Fig. 2 shows) to enclose the processing chamber 18 within the compartment 21 during operation.

The centrifuge station 20 rotates the processing chamber 18. When rotated, the processing chamber 18 centrifugally separates whole blood received from a donor into component parts, e.g., red blood cells, plasma, and platelets.

In the illustrated embodiment, the set 12 also includes a fluid pressure actuated cassette 28 (see Fig. 29). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. In the illustrated embodiment, the fluid pressure comprises positive and negative pneumatic pressure. Other types of fluid pressure can be used.

The cassette 28 can take various forms. In a preferred embodiment (see Fig. 29), the cassette 28 comprises an injection molded body 200 made of a rigid medical grade plastic material. Flexible diaphragms 202, preferably made of flexible sheets of medical grade plastic, overlay the front side and back sides of the cassette 28. The diaphragms are sealed about their peripheries to the peripheral edges of the front and back sides of the cassette 28.

As Fig. 29 shows, the cassette 28 has an array of interior cavities formed on both the front and back sides. The interior cavities define pneumatic pump stations (schematically designated PS in Fig. 3), which are interconnected by a pattern of fluid flow paths (schematically designated FP in Fig. 3) through an array of in line, pneumatic valves (schematically designated V in Fig. 3).

As Figs. 1 and 29 show, the cassette 28 interacts with a pneumatic actuated pump and valve station 30, which is mounted in the lid of the 40 of the case 36. The pump and valve station 30 includes a cassette holder 216. A door 32 is hinged to move with respect to the cassette holder 216 between an opened position, exposing the cassette holder 216 (shown in Fig. 1) for loading and unloading the cassette 28, and a closed position, enclosing the cassette 28 within the pump and valve station 30 for use (shown in Fig. 2). The pump and valve

station 30 includes pneumatic actuator ports 204 (see Fig. 29) that apply positive and negative pneumatic pressure upon the diaphragms of the cassette 28. The pneumatic pressures displace the diaphragms 202 with respect to the pump chambers and valves, to thereby direct liquid flow through the cassette 28.

Further details of the cassette 28 and the operation of the pump and valve station 30 can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

Referred back to Fig. 3, the flow set 16 also includes an array of tubes and containers in flow communication with the cassette 28. The arrangement of tubes and containers can vary according to the processing objectives. The system 10 can be operated to collect red blood cells, plasma, red blood cells and plasma, and platelets.

In the illustrated embodiment, the flow set 16 is arranged to support the centrifugal collection of two units of red blood cells (about 360 ml), and to filter the red blood cells to reduce the number of leukocytes prior to storage. During this procedure, whole blood from a donor is centrifugally processed in the chamber 18 into red blood cells (in which a majority of the leukocytes resides) and a plasma constituent (in which a majority of the platelets resides). The plasma constituent is returned to the donor, while the targeted volume of red blood cells is collected, filtered to reduce the population of leukocytes, and placed into containers for storage mixed with a red blood cell storage solution.

In this configuration (see Fig. 3), the flow set 16 includes a donor tube 266 having an attached phlebotomy needle 268. The donor tube 266 is coupled to a port of the cassette 28.

As Fig. 3 shows, a pressure cuff 58 is desirable used to enhance venous blood flow through the phlebotomy needle 268 during blood processing. The pressure cuff 58 is coupled to the pressure cuff port 56 on the lid 40 (as previously described), and the pressure supplied to the  
5 cuff 58 is desirably controlled by the controller 16. The controller 16 can also operate a vein pressure display 62 (see Fig. 26), which shows vein pressure at the pressure cuff 56.

10 An anticoagulant tube 270 is coupled to the phlebotomy needle 268. The anticoagulant tube 270 is coupled to another cassette port. A container 276 holding anticoagulant is coupled via a tube 274 to another cassette port.

15 A container 288 holding saline is coupled via a tube 284 to another cassette port.

The set 16 further includes tubes 290, 292, 294, which extend to an umbilicus 296. When installed in the processing station, the umbilicus 296 links the rotating  
20 processing chamber 18 with the cassette 28 without need for rotating seals. In a preferred embodiment, the umbilicus 296 is made from rotational-stress-resistant Hytrel® copolyester elastomers (DuPont). Further details of the construction of the umbilicus 296 will be provided  
25 later.

The tubes 290, 292, and 294 are coupled, respectively, to other cassette ports. The tube 290 conveys whole blood into the processing chamber 18. The tube 292 conveys plasma constituent from the processing  
30 chamber 18. The tube 294 conveys red blood cells from processing chamber 18.

A plasma collection reservoir 304 is coupled by a tube 302 to a cassette port. The collection reservoir 304 is intended, in use, to serve as a reservoir for the  
35 plasma constituent during processing prior to its return

to the donor.

A red blood cell collection reservoir 308 is coupled by a tube 306 to a cassette port. The collection reservoir 308 is intended, in use, to receive red blood  
5 cells during processing. for storage.

Two red blood cell storage containers 307 and 309 are coupled by a tube 311 to another cassette port. A leukocyte reduction filter 313 is carried in line by the tube 311. During processing, red blood cells are  
10 transferred from the red blood cell collection reservoir 308 through the filter 313 into the storage containers 307 and 309.

A container 208 holding a red blood cell storage or additive solution is coupled via a tube 278 to another  
15 cassette port. The red blood cell storage solution is metered into the red blood cells as they are conveyed from the container 308, through the filter 313, into the storage containers 307 and 309. Further details of this aspect of the collection process will be described later.

20 A whole blood reservoir 312 is coupled by a tube 310 to a cassette port. The collection container 312 is intended, in use, to serve as a reservoir for whole blood during processing.

In the illustrated embodiment, the set 16 further  
25 includes a fixture 338 (see Fig. 4) to hold the tubes 292 and 294 in viewing alignment with an optical sensing station 332 in the base 36 (see Fig. 12). The sensing station 332 optically monitors the presence or absence of targeted blood components (e.g., platelets and red blood  
30 cells) conveyed by the tubes 292 and 294. The sensing station 332 provides output reflecting the presence or absence of such blood components. This output is conveyed to the controller 16. The controller 16 processes the output and generates signals to control processing events  
35 based, in part, upon the optically sensed events. Further



details of the operation of the controller to control processing events based upon optical sensing can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

5           As Fig. 12 shows, the sensing station 332 is desirably located within the confines of the centrifuge station 20. This arrangement minimizes the fluid volume of components leaving the chamber before monitoring by the sensing station 332.

10           The fixture 338 gathers the tubes 292 and 294 in a compact, organized, side-by-side array, to be placed and removed as a group in association with the sensing station 332. In the illustrated embodiment, the fixture 338 also holds the tube 290, which conveys whole blood  
15           into the processing chamber 18, even though no associated sensor is provided. The fixture 338 serves to gather and hold all tubes 290, 292, and 294 that are coupled to the umbilicus 296 in a compact and easily handled bundle.

          The fixture 338 can be an integral part of the  
20           umbilicus 296, formed, e.g., by over molding. Alternatively, the fixture 338 can be a separately fabricated part, which snap fits about the tubes 290, 292, and 294 for use.

          As Figs. 1 and 2 also show, the case 36 contains  
25           other components compactly arranged to aid blood processing. In addition to the centrifuge station 20 and pump and valve station 30, already described, the case 36 includes a weigh station 238 and one or more trays 212 or hangers 248 for containers. The arrangement of these  
30           components in the case 36 can vary.

          In the illustrated embodiment, the weigh station 238 comprises a series of container hangers/weigh sensors 246 arranged along the top of the lid 40. In use, the containers 304, 308, 312 are suspended on the  
35           hangers/weigh sensors 246.

The holding trays 212 comprise molded recesses in the base 38. The trays 212 accommodate the containers 276 (containing anticoagulant) and 208 (containing the red blood cell additive solution). In the illustrated embodiment, an additional swing-out side hanger 248 is also provided on the side of the lid 40. The hanger 248 (see Fig. 2) supports the container 288 (containing saline) during processing. Other swing out hangers 249 support the red blood cells storage containers 307 and 309.

In the illustrated embodiment, the tray 212 holding the container 276 and the hanger 248 also include weigh sensors 246.

As blood or liquids are received into and/or dispensed from the containers during processing, the weigh sensors 246 provide output reflecting weight changes over time. This output is conveyed to the controller 16. The controller 16 processes the incremental weight changes to derive fluid processing volumes. The controller generates signals to control processing events based, in part, upon the derived processing volumes. Further details of the operation of the controller to control processing events can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

#### C. The Centrifugal Processing Chamber

Figs. 5 to 7 show an embodiment of the centrifugal processing chamber 18, which can be used in association with the system 10 shown in Fig. 1 to perform the intended red blood cell collection procedure. In the illustrated embodiment, the processing chamber 18 is preformed in a desired shape and configuration, e.g., by injection molding, from a rigid, biocompatible plastic material, such as a non-plasticized medical grade acrylonitrile-butadiene-styrene (ABS).

- 16 -

In one arrangement, the chamber 18 can be fabricated in two separately molded pieces; namely (as Figs. 5 to 7 show), a base 388 and a lid 150. The base 388 includes a center hub 120. The hub 120 is surrounded radially by  
5 inside and outside annular walls 122 and 124. Between them, the inside and outside annular walls 122 and 124 define a circumferential blood separation channel 126. A molded annular wall 148 closes the bottom of the channel 126.

10 The top of the channel 126 is closed by the separately molded, flat lid 150 (which is shown separated in Fig. 5 for the purpose of illustration). During assembly (see Fig. 7), the lid 150 is secured to the top of the chamber 18, e.g., by use of a cylindrical sonic  
15 welding horn.

All contours, ports, channels, and walls that affect the blood separation process may be preformed in the base 388 in a single, injection molded operation, during which molding mandrels are inserted and removed through the  
20 open end of the base 388 (shown in Fig. 5). The lid 150 comprises a simple flat part that can be easily welded to the open end of the base 388 to close it after molding. Because all features that affect the separation process are incorporated into one injection molded component, any  
25 tolerance differences between the base 388 and the lid 150 will not affect the separation efficiencies of the chamber 18.

The contours, ports, channels, and walls that are preformed in the base 388 may create surfaces within the  
30 base 388 that do not readily permit the insertion and removal of molding mandrels through a single end of the base 388. In this arrangement, the base 388 can be formed by separate molded parts, either by nesting cup shaped subassemblies or two symmetric halves.

35 Alternatively, molding mandrels can be inserted and

removed from both ends of the base 388. In this arrangement (see Fig. 8), the chamber 18 can be molded in three pieces; namely, the base 388, the lid 150 (which closes one end of the base 388 through which top molding  
5 mandrels are inserted and removed), and a separately molded insert 151 (which closes the other end of the base 388 through which bottom molding mandrels are inserted and removed).

The contours, ports, channels, and walls that are  
10 preformed in the base 388 can vary.

As seen in Fig. 9, in one arrangement, the inside annular wall 122 is open between one pair of stiffening walls. The opposing stiffening walls form an open interior region 134 in the hub 120, which communicates  
15 with the channel 126. Blood and fluids are introduced from the umbilicus 296 into and out of the separation channel 126 through this region 134.

In this embodiment (as Fig. 9 shows), a molded interior wall 136 formed inside the region 134 extends  
20 entirely across the channel 126, joining the outside annular wall 124. The wall 136 forms a terminus in the separation channel 126, which interrupts flow circumferentially along the channel 126 during separation.

Additional molded interior walls divide the region  
25 134 into three passages 142, 144, and 146. The passages 142, 144, and 146 extend from the hub 120 and communicate with the channel 126 on opposite sides of the terminus wall 136. Blood and other fluids are directed from the  
30 hub 120 into and out of the channel 126 through these passages 142, 144, and 146.

The underside of the base 388 (see Fig. 7) includes a shaped receptacle 179. The far end of the umbilicus 296 includes a shaped mount 178 (see Figs. 24 and 24A). The  
35 mount 178 is shaped to correspond to the shape of the

receptacle 179. The mount 178 can thus be plugged into the receptacle 179 (as Fig. 7 shows), to couple the umbilicus 296 in fluid communication with the channel 126.

5           The mount 178 is desirably made from a material that can withstand considerable flexing and twisting, to which the mount 178 can be subjected during use, e.g., Hytrel® 3078 copolyester elastomer (DuPont). The dimensions of the shaped receptacle 179 and the shaped mount 178 are  
10       preferably selected to provide a tight, dry press fit, to thereby avoid the need for solvent bonding or ultrasonic welding techniques between the mount 178 and the base 388 (which can therefore be formed from an incompatible material, such as ABS plastic).

15           **D.     The Centrifuge Assembly**

          The centrifuge station 20 (see Fig. 10) includes a centrifuge assembly 48. The centrifuge assembly 48 is constructed to receive and support the molded processing chamber 18 and umbilicus 296 for use.

20           As illustrated (see Figs. 10 and 11), the centrifuge assembly 48 includes a yoke 154 having bottom, top, and side walls 156, 158, 160. The yoke 154 spins on a bearing element 162 (Fig. 11) attached to the bottom wall 156. An electric drive motor 164 is coupled to the bottom  
25       wall 156 of the yoke 154, to rotate the yoke 154 about an axis 64. In the illustrated embodiment, the axis 64 is essentially horizontal (see Fig. 1), although other angular orientations can be used.

          A rotor plate 166 (see Fig. 11) spins within the  
30       yoke 154 about its own bearing element 168, which is attached to the top wall 158 of the yoke 154. The rotor plate 166 spins about an axis that is generally aligned with the axis of rotation 64 of the yoke 154.

          As Fig. 7 best shows, the top of the processing  
35       chamber 18 includes an annular lip 380, to which the lid

150 is secured. As Fig. 12 shows, the rotor plate 166 includes a latching assembly 382 that removably grips the lip 380, to secure the processing chamber 18 on the rotor plate 166 for rotation.

5           The configuration of the latching assembly 382 can vary. In the illustrated embodiment (see Figs. 13 to 15), the latching assembly 382 includes a latch arm 66 pivotally mounted on a pin in a peripheral recess 68 in the rotor plate 166. The latch arm 66 pivots between a  
10   retaining position (shown in Figs. 13 and 14) and a releasing position (shown in Fig. 15).

          In the retaining position (see Fig. 14), an annular groove 70 on the underside of the latch arm 66 engages the annular lip 380 of the processing chamber 18. The  
15   annular groove 70 on the latch arm 66 coincides with an annular groove 71 that encircles the top interior surface of the rotor plate 166. The engagement of the lip 380 within the groove 70/71 secures the processing chamber 18 to the rotor plate 166.

20           In the releasing position (see Fig. 15), the annular groove 70 is swung free of engagement of the annular lip 380. This lack of engagement allows release of the processing chamber 18 from the remainder of the groove 71 in the rotor plate 166.

25           In the illustrated embodiment, the latching assembly 382 includes a sliding pawl 72 carried in a radial track 74 on the top of the rotor plate. In the track 74, the pawl 72 slides radially toward and away from the latch arm 66.

30           When the latch arm 66 is in its retaining position and the pawl 72 is located in a radial position adjacent the latch arm 66 (see Fig. 14), a finger 76 on the pawl 72 slips into and engages a cam recess 78 in the latch arm 66. The engagement between the pawl finger 76 and  
35   latch arm cam recess 78 physically resists movement of

the latch arm 66 toward the releasing position, thereby locking the latch arm 66 in the retaining position.

5 A spring 80 within the pawl 72 normally biases the pawl 72 toward this radial position adjacent the latch arm 66, where engagement between the pawl finger 76 and latch arm cam recess 78 can occur. The latch arm 66 is thereby normally held by the pawl 72 in a locked, retaining position, to hold the processing chamber 18 during use.

10 The pawl 72 can be manually moved against the bias of the spring 80 radially away from its position adjacent the latch arm 66 (see Fig. 15). During this movement, the finger 76 on the pawl 72 slips free of the cam recess 78 in the latch arm 66. Free of engagement between the pawl  
15 finger 76 and latch arm cam recess 78, the latch arm 66 is unlocked and can be pivoted toward its releasing position. In the absence of manual force against the bias of the spring 80, the pawl 72 returns by spring force toward its position adjacent the latch arm 66, to  
20 lock the latch arm 66 in the chamber retaining position.

In the illustrated embodiment (see Fig. 13), the top wall 158 of the yoke 154 carries a downward depending collar 82. The collar 82 rotates in unison with the yoke 154, relative to the rotor plate 166. The collar 82  
25 includes a sidewall 84 that is continuous, except for a cut away or open region 86.

As Fig. 17 best shows, the pawl 72 includes an upstanding key element 88. The sidewall 84 of the collar 82 is located in the radial path that the key element 88  
30 travels when the pawl 72 is manually moved against the bias of the spring 80 radially away from its position adjacent the latch arm 66. The key element 88 abuts against the collar sidewall 84, to inhibit movement of the pawl 72 in this direction, unless the open region 86  
35 is aligned with the key element 88, as shown in Figs. 13

and 15. The open region 86 accommodates passage of the key element 88, permitting manual movement of the pawl 72 against the bias of the spring 80 radially away from its position adjacent the latch arm 66, thereby allowing the  
5 latch arm 66 to pivot into its releasing position.

The interference between the collar sidewall 84 and the key element 88 of the pawl 72 prevents manual movement of the pawl 72 away from the latch arm 66, to unlock the latch arm 66 for movement into its releasing  
10 position, unless the open region 86 and the key element 88 register. The open region 86 is aligned on the yoke 154 so that this registration between the open region 86 and the key element 88 occurs only when the rotor plate 166 is in a prescribed rotational position relative to  
15 the yoke 154. In this position (see Fig. 12), the sidewalls 160 of the yoke 154 are located generally parallel to the plane of the opening to the compartment, providing open access to the interior of the yoke 154. In this position (see Fig. 16), the processing chamber 18  
20 can be freely placed without interference into the interior of the yoke 154, and loaded onto the rotor plate 166. In this position, uninhibited manual movement of the pawl 72 allows the operator to pivot the latch arm 66 into its releasing position, to bring the lid 150 of the  
25 chamber 18 into contact against the rotor plate 166. Subsequent release of the pawl 72 returns the pawl 72 toward the latch arm 66 and allows the operator to lock the latch arm 66 in its retaining position about the lip 380 of the chamber 18. The reverse sequence is  
30 accommodated when it is time to remove the processing chamber 18 from the rotor plate 166.

This arrangement makes possible a straightforward sequence of acts to load the processing chamber 18 for use and to unload the processing chamber 18 after use  
35 (see Fig. 16). As Figs. 17 and 18 further show, easy



loading of the umbilicus 296 is also made possible in tandem with fitting the processing chamber 18 to the rotor plate 166.

5 A sheath 182 on the near end of the umbilicus 296 fits into a preformed, recessed pocket 184 in the centrifuge station 20. The pocket 184 holds the near end of the umbilicus 296 in a non-rotating stationary position aligned with the mutually aligned rotational axes 64 of the yoke 154 and rotor plate 166.

10 The preformed pocket 184 is also shaped to accommodate loading of the fixture 338 at the same time the sheath 182 is inserted. The tubes 290, 292, and 294 are thereby placed and removed as a group in association with the sensing station 332, which is located within the  
15 pocket 184.

Umbilicus support members 186 and 187 (see Fig. 12) are carried by a side wall 160 of the yoke 154. When the rotor plate 166 is located in its prescribed rotational position to enable easy loading of the chamber 18 (see  
20 Figs. 17 and 18), the support members 186 and 187 are presented on the left side of the processing chamber 18 to receive the umbilicus 296 at the same time that the sheath 182 and fixture 338 are manipulated for fitting into the pocket 184.

25 As Fig. 19 shows, one member 186 receives the mid portion of the umbilicus 296. The member 186 includes a surface 188 against which the mid portion of the umbilicus 296 rests. The surface 188 forms a channel that extends generally parallel to the rotational axis 64 and  
30 that accommodates passage of the mid portion of the umbilicus 296. The surface 188 inhibits travel of the mid portion of the umbilicus 296 in radial directions toward and away from the rotational axis 64. However, the surface 188 permits rotation or twisting of the  
35 umbilicus 296 about its own axis.

The other member 187 receives the upper portion of the umbilicus 296. The member 187 includes a surface 190 against which the upper portion of the umbilicus 296 rests. The surface 190 forms a channel inclined toward  
5 the top wall 158 of the yoke 154. The surface 190 guides the upper portion of the umbilicus 296 toward the recessed pocket 184, which is located axially above the top wall 158 of the yoke 154, where the umbilicus sheath 182 and fixture 338 are fitted. Like the surface 188, the  
10 surface 190 inhibits travel of the upper portion of the umbilicus 296 in radial directions toward and away from the rotational axis 64. However, like the surface 188, the surface 190 permits rotation or twisting of the umbilicus 296 about its own axis.

15 Closing the centrifuge station door 20 positions a holding bracket 90 on the underside of the door 20 in registry with the sheath 182 (see Figs. 17 and 18). Another holding bracket 92 on the underside of the door 20 is positioned in registry with the fixture 338 when  
20 the door 20 is closed. A releasable latch 94 preferably holds the door shut during operation of the centrifuge assembly 48.

During operation of the centrifuge assembly 48 (see Figs. 19 to 22), the support members 186 and 187 carry  
25 the umbilicus 296 so that rotation of the yoke 154 also rotates the umbilicus 296 in tandem about the yoke axis. Constrained within the pocket 184 at its near end (i.e., at the sheath 182) and coupled to the chamber 16 at its far end (i.e., by the mount 178), the umbilicus 296  
30 twists upon the surfaces 188 and 190 about its own axis as it rotates about the yoke axis 64, even as the surfaces 188 and 190 inhibit radial travel of the umbilicus relative to the rotation axis 64. The twirling of the umbilicus 296 about its axis as it rotates upon  
35 the surfaces 188 and 190 at one omega with the yoke 154

(typically at a speed of about 2250 RPM) imparts a two omega rotation to the processing chamber 18 secured for rotation on the rotor plate 166.

5 The relative rotation of the yoke 154 at a one omega rotational speed and the rotor plate 166 at a two omega rotational speed, keeps the umbilicus 296 untwisted, avoiding the need for rotating seals. The illustrated arrangement also allows a single drive motor 164 to impart rotation, through the umbilicus 296, to the  
10 mutually rotating yoke 154 and processing chamber 18 carried on the rotor plate 166. Further details of this arrangement are disclosed in Brown et al U.S. Patent 4,120,449, which is incorporated herein by reference.

15 The umbilicus 296 can stretch in response to the rotational forces it encounters. The dimensions of a given umbilicus 296 are also subject to normal manufacturing tolerances. These factors affect the flight radius of the umbilicus 296 during use; as well as the stress encountered by the mount 178 at the far end of the  
20 umbilicus 296, which serves as the two omega torque transmitter to drive the processing chamber 18; as well as the lateral loads acting on the centrifuge and motor bearings.

25 As Figs. 19 to 22 show, the support members 186 and 187 on the yoke serve to physically confine the flight of the umbilicus 296 between the one omega region (mid portion) and two omega region (far end portion), as well as between the one omega region (mid portion) and zero omega region (near end portion) of the umbilicus 296. By  
30 confining the umbilicus 296 to a predefined radial distance from and radial orientation with respect to the rotational axis of the centrifuge assembly 48, the support members 186 and 187 serve to attenuate the factors that can affect umbilicus performance and  
35 endurance.

The support members 186 and 187 make possible a bearing-less umbilicus assembly with no moving parts, while leading to reduced stress at the two omega torque region, where stresses tend to be greatest. The surfaces 188 and 190 of the support members 186 and 187 can be formed and oriented to accommodate rotation of the umbilicus 296 and the driving of the processing chamber 18 in either clockwise or counterclockwise directions.

In the illustrated embodiment, the surfaces 188 and 190 of the support members 186 and 187 are preferably fabricated from a low friction material, to thereby eliminate the need for external lubrication or rotating bearings on the umbilicus 296 itself. The material used can, e.g., comprise Teflon® polytetrafluoroethylene material (DuPont) or an ultra high molecular weight polyethylene. Made from such materials, the surfaces 188 and 190 minimize umbilicus drive friction and the presence of particulate matter due to umbilicus wear.

In a representative embodiment (see Fig. 4), the umbilicus 296 desirably comprises a two layer co-extruded assembly. The interior or core layer 96 desirably comprises Hytrel® 4056 copolyester elastomer (DuPont). The outside layer 98 desirably comprises Hytrel® 3078 copolyester elastomer (DuPont). The outside layer 98 may comprise a relatively thin extrusion, compared to the core layer 96.

In this arrangement, the outside layer 98 of Hytrel® 3078 copolyester elastomer serves as a compatible interface to accommodate over-molding of the zero omega sheath 182 and the two omega mount 178, which may comprise the same Hytrel® 3078 material or an otherwise compatible material. Absent material compatibility, solvents (e.g., methylene chloride) or other forms of surface treatment may be required to facilitate a robust bond between these elements and the umbilicus. Hytrel®

3078 material is desired for the sheath 182, and the mount 178 because it can withstand considerable flexing and twisting forces, to which these regions of the umbilicus are subjected during use.

5       The core layer 96 of Hytrel® 4056 copolyester elastomer can be readily solvent bonded to conventional flexible medical grade polyvinyl tubing, from which the tubes 290, 292, and 294 are desirably made.

## II. Double Red Blood Cell Collection Procedure

10       Use of the set 12 in association with the device 14 and controller 16 to conduct a typical double unit red blood cell collection procedure will now be described for illustrative purposes.

### A. The Cassette

15       The cassette 28 used for a procedure of this type desirably includes dual pneumatic pump chambers PP3 and PP4 (see Fig. 23) which are operated by the controller 16 in tandem to serve as a general purpose, donor interface pump. The dual donor interface pump chambers PP3 and PP4  
20       work in parallel. One pump chamber draws fluid, while the other pump chamber expels fluid. The dual pump chambers PP3 and PP4 thereby alternate draw and expel functions to provide a uniform outlet flow.

25       The cassette 28 also desirably includes a pneumatic pump chamber PP5, which serves as a dedicated anticoagulant pump, to draw anticoagulant from the container 276 and meter the anticoagulant into the blood drawn from the donor.

30       The cassette 28 also desirably includes a pneumatic pump chamber PP1 that serves as a dedicated in-process whole blood pump, to convey whole blood from the reservoir 312 into the processing chamber 18. The dedicated function of the pump chamber PP1 frees the donor interface pump chambers PP3 and PP4 from the added  
35       function of supplying whole blood to the processing

chamber 18. Thus, the in-process whole blood pump chamber PP1 can maintain a continuous supply of blood to the processing chamber 18, while the donor interface pump chambers PP3 and PP4 operate in tandem to simultaneously  
5 draw and return blood to the donor through the single phlebotomy needle. Processing time is thereby minimized.

The cassette 28 also desirably includes a pneumatic pump chamber PP2 that serves as a plasma pump, to convey plasma from the processing chamber 18. The ability to  
10 dedicate separate pumping functions provides a continuous flow of blood into and out of the processing chamber 18, as well as to and from the donor.

#### B. Capacitive Flow Sensing

The controller 16 desirably includes means for  
15 monitoring fluid flow through the pump chambers PP1 to PP5. In the illustrated embodiment, the pump and valve station 30 carries electrode circuits 206 associated with each pump chamber PP1 to PP5. The electrode circuits 206 can be located, e.g., within the pneumatic actuator ports  
20 204 in the pump and valve station 30 (see Fig. 29) that apply negative and positive pressure to the diaphragms to thereby draw fluid into the chambers PP1 to PP5 and expel fluid from the chambers PP1 to PP5. The electrode circuits 206 are coupled to an electrical source and are  
25 in electrical conductive contact with fluids within their respective pump chambers PP1 and PP5.

The passage of electrical energy through each electrode circuit 206 creates an electrical field within the respective pump chamber PP1 to PP5. Cyclic deflection  
30 of the diaphragm associated with a given pump chamber to draw fluid into and expel fluid from the pump chamber PP1 to PP5 changes the electrical field, resulting in a change in total capacitance of the circuit through the electrode. Capacitance increases as fluid is draw into  
35 the pump chamber PP1 to PP5, and capacitance decreases as

fluid is expelled from pump chamber PP1 to PP5.

In the arrangement, the electrode circuits 206 each includes a capacitive sensor (e.g., a Qprox E2S). The capacitive sensor registers changes in capacitance for  
5 the electrode circuit 206 for each pump chamber PP1 to PP5. The capacitance signal for a given electrode circuit 206 has a high signal magnitude when the pump chamber is filled with liquid, has a low signal magnitude signal when the pump chamber is empty of fluid, and has a range  
10 of intermediate signal magnitudes when the diaphragm occupies intermediate positions.

At the outset of a blood processing procedure, the controller 16 can calibrate the difference between the high and low signal magnitudes for each sensor to the  
15 maximum stroke volume of the respective pump chamber. The controller 16 can then relate the difference between sensed maximum and minimum signal values during subsequent draw and expel cycles to fluid volume drawn and expelled through the pump chamber. The controller 16  
20 can sum the fluid volumes pumped over a sample time period to yield an actual flow rate.

The controller 16 can compare the actual flow rate to a desired flow rate. If a deviance exists, the controller 16 can vary pneumatic pressure pulses  
25 delivered to the actuators for the pump chambers PP1 to PP5 to minimize the deviance.

The controller 16 can also operate to detect abnormal operating conditions based upon the variations in the electric field and to generate corresponding alarm  
30 outputs. The controller 16 can, e.g., monitor for an increase in the magnitude of the low signal magnitude over time. The increase in magnitude reflects the presence of air inside a pump chamber.

For example, the controller 16 can generate a  
35 derivative of the signal output of the sensor 426.

Changes in the derivative, or the absence of a derivative, reflects a partial or complete occlusion of flow through the pump chamber PP1 to PP5. The derivative itself also varies in a distinct fashion depending upon whether the occlusion occurs at the inlet or outlet of the pump chamber PP1 to PP5.

#### 1. Monitoring Vein Flow Conditions

By using capacitive sensing and by also counting pump strokes (i.e., the application of negative pressure upon the diaphragm of a given pump chamber to draw fluid into the chamber), the controller 16 can also monitor vein flow conditions, and, in particular, assess and respond to real or potential vein occlusion conditions.

When blood is pumped from the donor, the donor's vein may show difficulties in keeping up with the commanded draw rate that operation of the donor pump chambers PP3/PP4 imposes. In the case of restricted blood flow from the donor, the donor pumps PP3 and PP4 do not fill properly in response to the commanded sequence of pump strokes. The controller 16 attempts to assess and mediate blood supply interruptions due to vein problems before generating a vein occlusion alarm, which suspends processing.

For example, the controller 16 can count the number of consecutive attempted pump strokes for which no blood flow into the pump chambers PP3 and PP4 occurs (which blood flow or absence of blood flow can be detected by capacitive sensing, as above described). A potential donor draw occlusion condition can be deemed to occur when a prescribed number (e.g., 3) of consecutive incomplete fill donor pump strokes takes place.

When a potential donor draw occlusion condition is detected, the controller 16 attempts to rectify the condition by increasing pressure of the pressure cuff 58 and/or decreasing the commanded draw rate, before



generating a processing-halting vein occlusion alarm.

More particularly, in a representative implementation, when a donor draw occlusion condition is detected, the controller 16 executes a potential draw occlusion condition function (in shorthand, the "Potential Occlusion Function"). The Potential Occlusion Function first suspends the draw for a period of time (e.g. upwards to 20 seconds, and desirably about 10 seconds) to rest the vein. While the vein rests, the controller 16 also increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg), unless cuff pressure, when adjusted, exceeds a prescribed maximum (e.g., upwards to 100 mmHg, desirably about 70 mmHg). If the prescribed maximum cuff pressure condition exists, no incremental changes to the cuff pressure are made during the prescribed vein rest interval.

After the prescribed vein rest interval, the Potential Occlusion Function resets the attempted pump stroke counter to zero and resumes the draw cycle. The controller 16 monitors the initial series of consecutive pump strokes during the resumed draw cycle, up to a first threshold number of pump strokes (e.g., 5). The magnitude of the first threshold number is larger than the number of consecutive incomplete fill donor pump strokes (i.e., 3) that indicate a potential donor draw occlusion condition. The magnitude of the first threshold number is selected to accurately assess, after a potential donor draw occlusion condition arises, whether a true donor draw occlusion exists. In the illustrated embodiment, if within the first five pump strokes (or whatever the first threshold number is), three consecutive incomplete fill donor pump strokes take place, the controller 16 assumes that a true donor draw occlusion exists, and thus generates an occlusion alarm. With the generation of an

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occlusion alarm, the controller 16 suspends processing, until the operator can establish that it is safe to resume.

5 If within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes do not take place, the controller 16 assumes that a true vein occlusion may not exist, and that the potential occluded flow condition was either transient, or at least capable of correction short of suspending the  
10 procedure. In this event, the Potential Occlusion Function allows the resumed draw cycle to continue beyond the first threshold number of pump strokes up to a second threshold number of pump strokes (e.g., 20 to 100, and desirable about 50).

15 If at any time between the first threshold number of pump strokes and the second threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the Potential Occlusion Function institutes another vein rest interval(e.g. upwards to 20  
20 seconds, and desirably about 10 seconds). While the vein rests, the Potential Occlusion Function also again increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg). While the vein rests, the Potential Occlusion  
25 Function also lowers the draw rate by a preset decrement (e.g., upwards to 20 ml/min, and desirably about 10 ml/min). If the draw rate, when lowered, is less than a prescribed minimum draw rate (e.g., 70 to 90 ml/min), the controller 16 generates an occlusion alarm. Otherwise,  
30 the Potential Occlusion Function resets the attempted pump stroke counter to zero, and resumes the draw cycle at the increased cuff pressure and decreased draw rate.

The controller 16 again monitors the initial series of consecutive pump strokes during the resumed draw  
35 cycle, up to the first threshold number of pump strokes

(e.g., 5). If within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the controller 16 assumes that a true donor draw occlusion exists, and thus generates an occlusion alarm and also suspends processing.

However, if within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes do not take place, the controller 16 allows the resumed draw cycle to continue beyond the first threshold number of pump strokes up to the second threshold number of pump strokes (e.g., 20 to 100, and desirable about 50). If at any time between the first threshold number of pump strokes and the second threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the Potential Occlusion Function again institutes another vein rest interval (e.g. upwards to 20 seconds, and desirably about 10 seconds). While the vein rests, the Potential Occlusion Function also again increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg). While the vein rests, the Potential Occlusion Function also again lowers the draw rate by a preset decrement (e.g., upwards to 20 ml/min, and desirably about 10 ml/min), unless the draw rate, when lowered, is less than a prescribed minimum draw rate (e.g., 70 to 90 ml/min), in which case the controller 16 generates an occlusion alarm. Otherwise, the Potential Occlusion Function resets the attempted pump stroke counter to zero, and resumes the draw cycle at the increased cuff pressure and decreased draw rate.

The controller 16 continues to repeat the steps of the Potential Occlusion Function, using the first and second pump stroke number thresholds to gage whether a true vein occlusion exists, and either generating an occlusion alarm if it does, or continuing to attempt

remedial action (by increasing cuff pressure and/or decreasing draw rate), or cancelling the potential donor draw occlusion condition when three consecutive incomplete fill donor pump strokes are not observed during either the first or second threshold periods following a potential donor occlusion condition.

If no three consecutive incomplete fill donor pump strokes take place within the second threshold number of strokes following a potential donor draw occlusion condition, the controller 16 assumes that a true vein occlusion does not exist. The draw cycle continues, and the controller 16 continues to count pump strokes. If the prescribed number (e.g., 3) of consecutive incomplete fill donor pump strokes subsequently takes place, the controller 16 assumes that this event is unrelated to any previous occlusion event condition, and generates a new potential donor draw occlusion condition, executing the Potential Occlusion Function from the start.

It should be appreciated that the Potential Occlusion Function, as just described, can be used with any blood processing device that has means for detecting when a draw blood pumping command does not result in blood flow through the pump.

#### C. Blood Processing Cycles

Prior to undertaking the double unit red blood cell collection procedure, as well as any blood collection procedure, the controller 16 conducts an appropriate integrity check of the cassette 28, to determine whether there are any leaks in the cassette 28. Once the cassette integrity check is complete and no leaks are found, the controller 16 begins the desired blood collection procedure.

In general, using the processing chamber shown in Fig. 9), whole blood is introduced into and separated within the processing chamber 18 as it rotates. As the

processing chamber 18 rotates (arrow R in Fig. 9), the umbilicus 296 conveys whole blood into the channel 126 through the passage 146. The whole blood flows in the channel 126 in the same direction as rotation (which is counterclockwise in Fig. 9). Alternatively, the chamber 18 can be rotated in a direction opposite to the circumferential flow of whole blood, i.e., clockwise, but rotation in the same direction as circumferential blood flow is preferred.

10       The whole blood separates as a result of centrifugal forces. Red blood cells are driven toward the high-G wall 124, while lighter plasma constituent is displaced toward the low-G wall 122. In this flow pattern, a dam 384 projects into the channel 126 toward the high-G wall 124. The dam 384 prevents passage of plasma, while allowing passage of red blood cells into a channel 386 recessed in the high-G wall 124. The channel 386 directs the red blood cells into the umbilicus 296 through the radial passage 144. The plasma constituent is conveyed from the channel 126 through the radial passage 142 into umbilicus 296.

#### 1. Collection Cycle

During a typical collection cycle of the double unit red blood cell collection procedure, whole blood drawn from the donor is processed to collect two units of red blood cells, while returning plasma to the donor. The donor interface pumps PP3/PP4 in the cassette, the anticoagulant pump P5 in the cassette, the in-process pump PP1 in the cassette, and the plasma pump PP2 in the cassette are pneumatically driven by the controller 16, in conjunction with associated pneumatic valves, to draw anticoagulated blood into the in-process container 312, while conveying the blood from the in-process container 312 into the processing chamber 18 for separation. This arrangement also removes plasma from the processing

chamber into the plasma container 304, while removing red blood cells from the processing chamber into the red blood cell container 308. This phase continues until an incremental volume of plasma is collected in the plasma  
5 collection container 304 (as monitored by a weigh sensor) or until a targeted volume of red blood cells is collected in the red blood cell collection container (as monitored by a weigh sensor).

If the volume of whole blood in the in-process  
10 container 312 reaches a predetermined maximum threshold before the targeted volume of either plasma or red blood cells is collected, the controller 16 terminates operation of the donor interface pumps PP3/PP4 to terminate collection of whole blood in the in-process  
15 container 312, while still continuing blood separation. If the volume of whole blood reaches a predetermined minimum threshold in the in-process container 312 during blood separation, but before the targeted volume of either plasma or red blood cells is collected, the  
20 controller 16 returns to drawing whole blood to thereby allow whole blood to enter the in-process container 312. The controller toggles between these two conditions according to the high and low volume thresholds for the in-process container 312, until the requisite volume of  
25 plasma has been collected, or until the target volume of red blood cells has been collected, whichever occurs first.

## 2. Return Cycle

During a typical return cycle (when the targeted  
30 volume of red blood cells has not been collected), the controller 16 operates the donor interface pumps PP3/PP4 within the cassette 28, the in-process pump PP1 within the cassette, and the plasma pump PP2 within the  
cassette, in conjunction with associated pneumatic  
35 valves, to convey anticoagulated whole blood from the in-

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process container 312 into the processing chamber 18 for separation, while removing plasma into the plasma container 304 and red blood cells into the red blood cell container 308. This arrangement also conveys plasma from the plasma container 304 to the donor, while also mixing saline from the container 288 in line with the returned plasma. The in line mixing of saline with plasma raises the saline temperature and improves donor comfort. This phase continues until the plasma container 304 is empty, as monitored by the weigh sensor.

If the volume of whole blood in the in-process container 312 reaches a specified low threshold before the plasma container 304 empties, the controller 16 terminates operation of the in-process pump PP1 to terminate blood separation. The phase continues until the plasma container 304 empties.

Upon emptying the plasma container 304, the controller 16 conducts another collection cycle. The controller 16 operates in successive collection and return cycles until the weigh sensor indicates that a desired volume of red blood cells have been collected in the red blood cell collection container 308. The controller 16 terminates the supply and removal of blood to and from the processing chamber, while operating the donor interface pumps PP3/PP4 in the cassette 28 to convey plasma remaining in the plasma container 304 to the donor. The controller 16 next operates the donor interface pumps PP3/PP4 in the cassette to convey the blood contents remaining in the in-process container 312 to the donor as well as convey saline to the donor, until a prescribed replacement volume amount is infused, as monitored by a weigh sensor.

### 3. . In-Line Leukofiltration Cycle

When the collection of red blood cells and the return of plasma and residual blood components has been

completed, the controller 16 switches, either automatically or after prompting the operator, to an in-line leukofiltration cycle. During this cycle, red blood cells are removed from the red blood cell collection reservoir 308 and conveyed into the red blood cell storage containers 307 and 308 through the leukocyte removal filter 313. At the same time, a desired volume of red blood cell storage solution from the container 208 is mixed with the red blood cells.

10 In the first stage of this cycle, the controller 16 operates donor interface pumps PP3/PP4 in the cassette to draw air from the red blood cell storage containers 307 and 309, the filter 313, and the line 311, and to transfer this air into the red blood cell collection reservoir 308. This stage minimizes the volume of air residing in the red blood cell storage containers 307 and 309 before the leukocyte removal process begins. The stage also provides a volume of air in the red blood cell collection container 308 that can be used purge red blood cells from the filter 313 into the red blood cell collection containers 307 and 309 once the leukocyte removal process is completed.

25 In the next stage, the controller 16 operates the donor interface pumps PP3/PP4 in the cassette 28 to draw a priming volume of storage solution from the solution container 208 into the red blood cell collection reservoir 308. This stage primes the tubing 278 between the container 208 and the cassette 28, to minimize the volume of air pumped into the final red blood cell storage containers 307 and 309.

35 In the next stage, the controller 16 operates the donor interface pumps PP3/PP4 in the cassette 28 to alternate pumping red blood cells from the red blood cell collection reservoir 308 into the red blood cell collection containers 307 and 309 (through the filter



313), with pumping of red blood cell storage solution from the container 208 into the red blood cell collection containers 307 and 309 (also through the filter 313). This alternating process mixes the storage solution with  
5 the red blood cells. The controller 16 counts the pneumatic pump strokes for red blood cells and the storage solution to obtain a desired ratio of red cell volume to storage solution volume (e.g., five pump strokes for red blood cells, followed by two pump strokes  
10 for storage solution, and repeating the alternating sequence). This alternating supply of red blood cells and storage solution continues until the weigh scale for the red blood cell collection reservoir 308 indicates that the reservoir 308 is empty.

15 When the red blood cell collection reservoir 308 is empty, the controller 16 operates the donor interface pumps PP3/PP4 to pump additional storage solution through the filter 313 and into the red blood storage containers 307 and 309, to ensure that a desired ratio between  
20 storage solution volume and red blood cell volume exists.

This also rinses residual red blood cells from the filter 313 into the red blood cell storage containers 307 and 309 to maximize post-filtration percent red blood cell recovery.

25 The controlled ratio of pump strokes for red blood cells and for storage solution that the controller 16 achieves ensures that the storage solution is always metered in at a constant ratio. Therefore, regardless of the volume of red blood cells collected, the final red  
30 blood cell / storage solution hematocrit can be constant.

The alternating supply of red blood cells and storage solution through the filter 313 eliminates the need to first drain the storage solution into the red blood cell collection reservoir 308, which lessens the  
35 overall procedure time.

The alternating supply of red blood cells and storage solution through the filter 313 also eliminates the need to manually agitate a red blood cell / storage solution mixture prior to leukofiltration. Due to  
5 density differences, when concentrated red blood cells are added to a preservation solution, or vice versa, the preservation solution floats to the top. Poorly mixed, high hematocrit, high viscosity red blood cells lead to reduced flow rates during leukofiltration. Poorly mixed,  
10 high hematocrit, high viscosity red blood cell conditions can also lead to hemolysis. By alternating passage of red blood cells and storage solution through the filter 313, mixing occurs automatically without operator involvement.

15 The alternating supply of red blood cells and storage solution through the filter 313 also eliminates the need to gravity drain the red blood cell product through the leukofilter 313. As a result, filtration can occur in about half the time required for a gravity-drain  
20 procedure.

If desired, the controller 16 can monitor weight changes relating to the red blood cell collection reservoir 308 and the red blood cell storage containers 307 and 309, to derive a value reflecting the percent of  
25 red blood cells that are recovered after passage through the leukofilter 313. This value can be communicated to the operator, e.g., on the display screen of user the user interface.

The following expression can be used to derive the  
30 percent recovery value:

$$\% \text{ Recovery} = [( \text{Bag A Vol} + \text{Bag B Vol} ) / \text{RBC Vol} + \text{Adsol} )] * 100$$

where:

Bag A Vol represents the volume of red blood cells  
35 collected the container 307, calculated as follows:

(Wt of Container 307 containing red blood cells(in  
g) - Container 307 Tare)/ 1.062 g/ml

Bag B Vol represents the volume of red blood cells  
collected the container 309, calculated as follows:

5 (Wt of Container 309 containing red blood cells(in  
g) - Container 309 Tare)/ 1.062 g/ml

RBC Vol represents the volume of red blood cells  
collected in the red blood cell collection reservoir 308,  
which the controller 16 determines by weight sensing at  
10 the end of the procedure.

Adsol represents the volume of red blood cell  
storage solution added to the during leukofiltration,  
which is determined by the controller 16 by capacitive  
sensing during processing.

15 a. The Leukofilter

The leukofilter 313 can be variously constructed.  
In the embodiment illustrated in Figs. 24A and 24B, the  
filter comprises a housing 100 inclosing a filtration  
medium 102 that can comprise a membrane or be made from a  
20 fibrous material. The filtration medium 102 can be  
arranged in a single layer or in a multiple layer stack.  
If fibrous, the medium 102 can include melt blown or spun  
bonded synthetic fibers (e.g., nylon or polyester or  
polypropylene), semi-synthetic fibers, regenerated  
25 fibers, or inorganic fibers. If fibrous, the medium 102  
removes leukocytes by depth filtration. If a membrane,  
the medium 102 removes leukocytes by exclusion.

The housing 100 can comprise rigid plastic plates  
sealed about their peripheries. In the illustrated  
30 embodiment, the housing 100 comprises first and second  
flexible sheets 104 of medical grade plastic material,  
such as polyvinyl chloride plasticized with di-2-  
ethylhexyl-phthalate (PVC-DEHP). Other medical grade  
plastic materials can be used that are not PVC and/or are  
35 DEHP-free.

In the illustrated embodiment, a unitary, continuous peripheral seal 106 (see Fig. 24B) is formed by the application of pressure and radio frequency heating in a single process to the two sheets 104 and filtration medium 102. The seal 106 joins the two sheets 104 to each other, as well as joins the filtration medium 102 to the two sheets 104. The seal 106 integrates the material of the filtration medium 102 and the material of the plastic sheets 104, for a reliable, robust, leak-proof boundary. Since the seal 106 is unitary and continuous, the possibility of blood shunting around the periphery of the filtration medium 102 is eliminated.

The filter 313 also includes inlet and outlet ports 108. The ports 108 can comprise tubes made of medical grade plastic material, like PVC-DEHP. In the embodiment shown in Fig. 24, the ports 108 comprise separately molded parts that are heat sealed by radio frequency energy over a hole 109 formed in the sheets 104 (see Fig. 24B).

In the illustrated embodiment (as Figs. 25A and 25B show), the filter 313 is desirably placed within a restraining fixture 110 during use. The fixture 110 restrains expansion of the flexible sheets 104 of the filter housing 100 as a result of pressure applied by pumping red blood cells through the filter 313. The fixture 110 keeps the total blood volume in the filter 313 at a minimum through the filtration process, thereby decreasing filtration time, as well as increasing the red blood cell recovery percentage following leukofiltration.

The fixture 110 can take various forms. In the illustrated embodiment, the fixture 110 comprises two plates 112 coupled by a hinge 114. The fixture 110 can be placed in an open condition (as Fig. 25A shows) to receive the filter 313 prior to leukofiltration, or to remove the filter 313 following leukofiltration. The

fixture 110 can also be placed in a closed condition (as Fig. 25B shows) to sandwich the filter 313 between the two plates 112. A releasably latch 116 holds the plates 112 in the closed condition for use.

5       The plates 112 maintain a desired gap clearance, thereby restraining expansion of the filter 313 during use. The gap clearance is selected to maintain a desired blood flow rate at a desired minimum blood volume.

10       The plates 112 desirably include indentations 118 in which the ports 108 of the filter 313 rest in a non-occluded condition when the fixture 110 is closed. The interior surfaces of the plates 112 may be roughed or scored with a finish to aid blood flow through the filter 313 when the fixture 110 is closed.

15       The fixture 110 can be made as a stand-alone item that can be separately stored prior to use. It can be stored in association with the device 14 during transport and prior to use, e.g., in a receptacle 128 formed on the exterior of the lid 40 of the device 14 (see Fig. 26).  
20       The fixture 110 can include a mounting bracket 130 (see Fig. 28) that, e.g., slidably engages a mating mounting track 132, to hold the fixture 110 in the receptacle 128 prior to use (shown in phantom lines in Fig. 26) or to secure the fixture 110 on the base 38 as leukofiltration  
25       is carried out (see Fig. 27).

      It should be appreciated that pump-assisted leukofiltration of red blood cells, whole blood, or other blood cell products, wherein blood flow through a leukofilter is not driven strictly by gravity flow, can  
30       be carried out using manual or automated systems having configurations different than those shown in this Specification. For example, external peristaltic or fluid actuated pumping devices can be used to transfer whole blood or manually processed blood products from  
35       separation bags into processing or storage containers

through intermediate leukofiltration devices. It should also be appreciated that a filter restraining fixture of the type shown in Fig. 24B can also be used in association with any pump-assisted leukofiltration system. It should also be appreciated that a filter restraining fixture 110 can also be used in systems where blood flow through the leukofilter relies strictly upon gravity flow.

The many features of the invention have been demonstrated by describing their use in separating whole blood into component parts for storage and blood component therapy. This is because the invention is well adapted for use in carrying out these blood processing procedures. It should be appreciated, however, that the features of the invention equally lend themselves to use in other blood processing procedures.

For example, the systems and methods described, which make use of a programmable cassette in association with a blood processing chamber, can be used for the purpose of washing or salvaging blood cells during surgery, or for the purpose of conducting therapeutic plasma exchange, or in any other procedure where blood is circulated in an extracorporeal path for treatment.

Features of the invention are set forth in the following claims.

We Claim:

1. A blood processing system comprising  
a blood processing set including a source of  
blood cells, and a blood component collection flow  
5 channel coupled to the source of blood cells including a  
blood cell storage container and an in-line filter to  
remove leukocytes from the blood cells before entering  
the blood cell storage container, the in-line filter  
including a fibrous filter medium, first and second  
10 flexible housings, a unitary, continuous peripheral seal  
formed by application of pressure and radio-frequency  
heating in a single process to join the first and second  
flexible housings to each other, as well as join the  
fibrous filtration medium to the first and second  
15 flexible housings, and  
a pump station adapted to be placed into  
communication with the blood component collection flow  
channel to pump blood into the blood cell storage  
container through the in-line filter.
- 20 2. A blood processing system according to  
claim 1  
further including a fixture to restrain  
expansion of the first and second filter housings as a  
result of pressure applied during operation of the pump  
25 station.
3. A blood processing system according to  
claim 2  
wherein the source of blood cells includes a  
donor flow channel including a blood separation device to  
30 separate blood cells from donor whole blood.
4. A blood processing system according to  
claim 1  
wherein the source of blood cells includes a  
donor flow channel including a blood separation device to  
35 separate blood cells from donor whole blood.

5. A system according to claim 1 or 2 or 3  
or 4

wherein the controller includes a function to  
derive a value reflecting volume of blood cells present  
5 in the blood cell storage container after passage through  
the filter as a percentage of volume of blood cells  
conveyed to the filter.

6. A system according to claim 1 or 2 or 3  
or 4

10 wherein the pump station includes a fluid  
pressure actuated pump and an actuator to apply fluid  
pressure to the pump.

7. A system according to claim 1 or 2 or 3  
or 4

15 wherein the blood cells comprise red blood  
cells.

8. A method of processing blood comprising  
using the blood processing system as defined in claim 1  
or 2 or 3 or 4.

20



**ABSTRACT**

Systems and methods separate pump the blood cells through an in-line leukofilter to a blood cell storage container. The leukofilter has a filtration medium enclosed within a flexile housing. The systems and methods can employ a fixture to restrain expansion of the flexible filter housing during operation of the pump.



FIG. 2

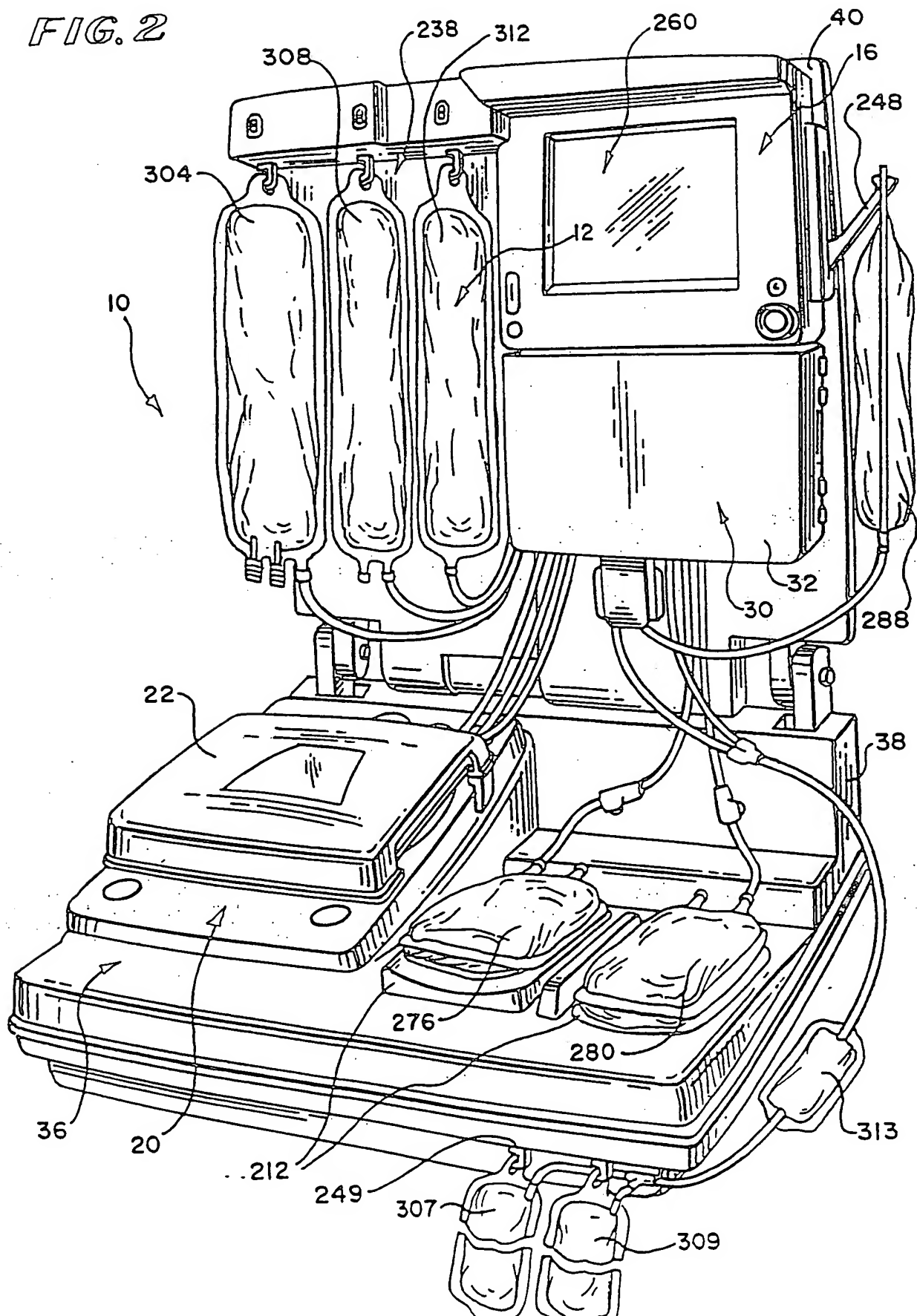


FIG. 3

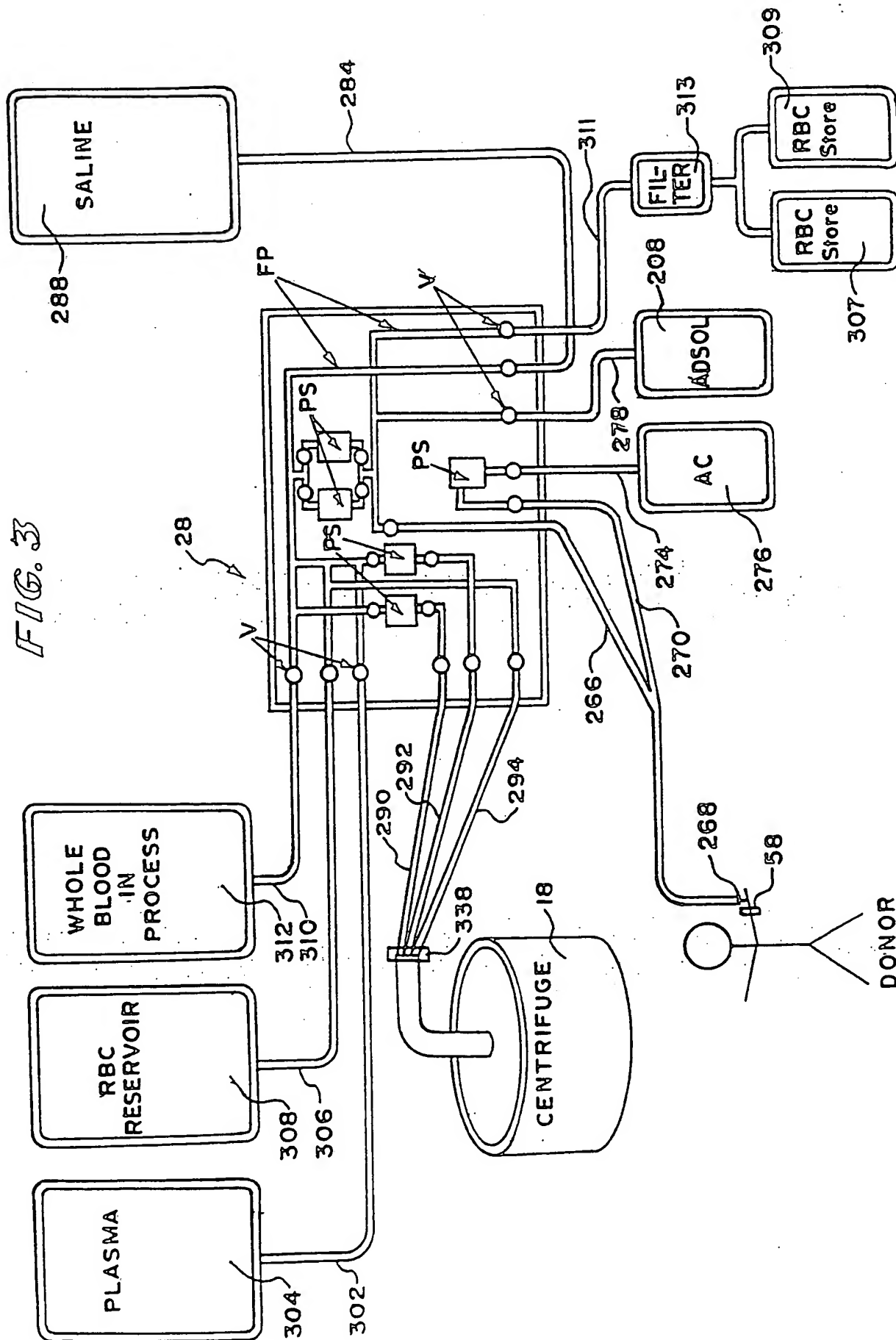
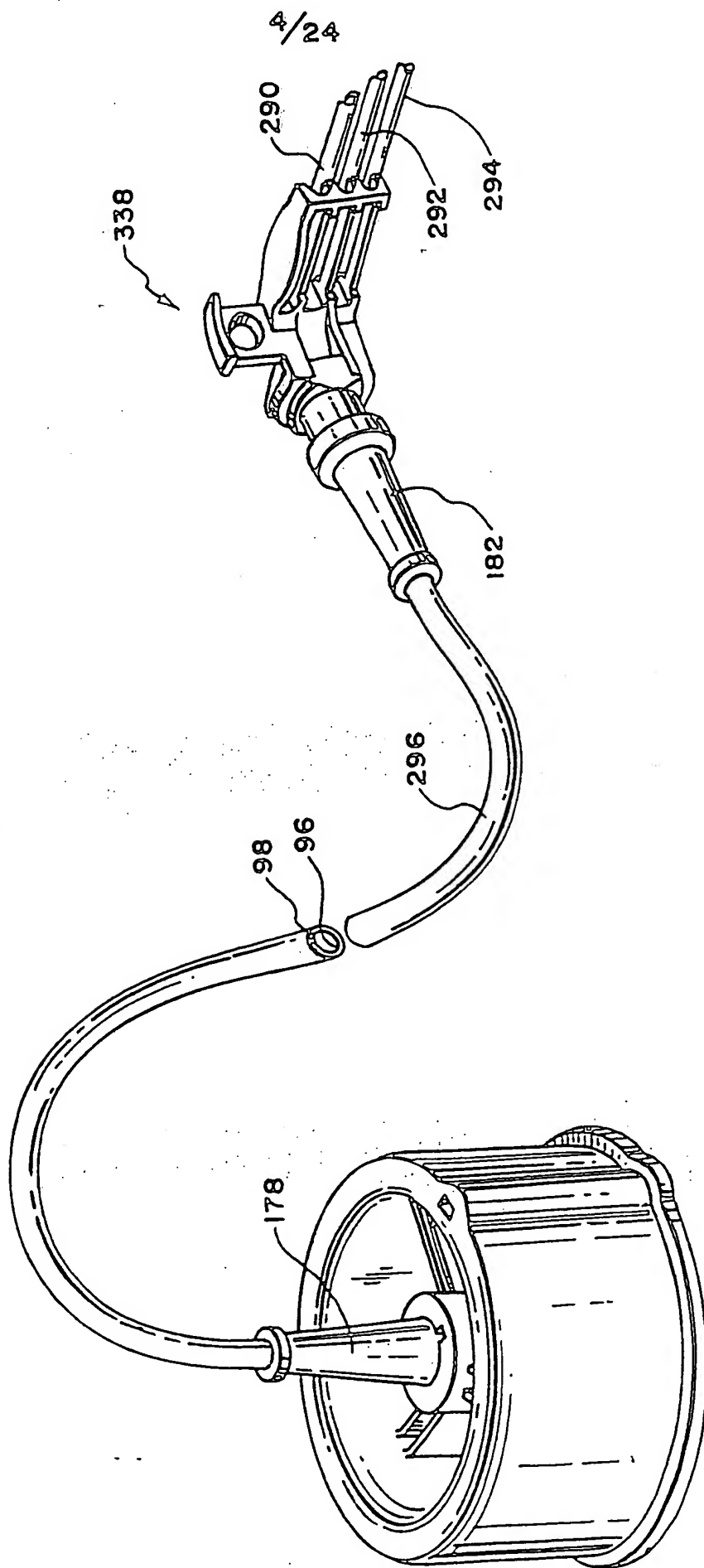


FIG. 4



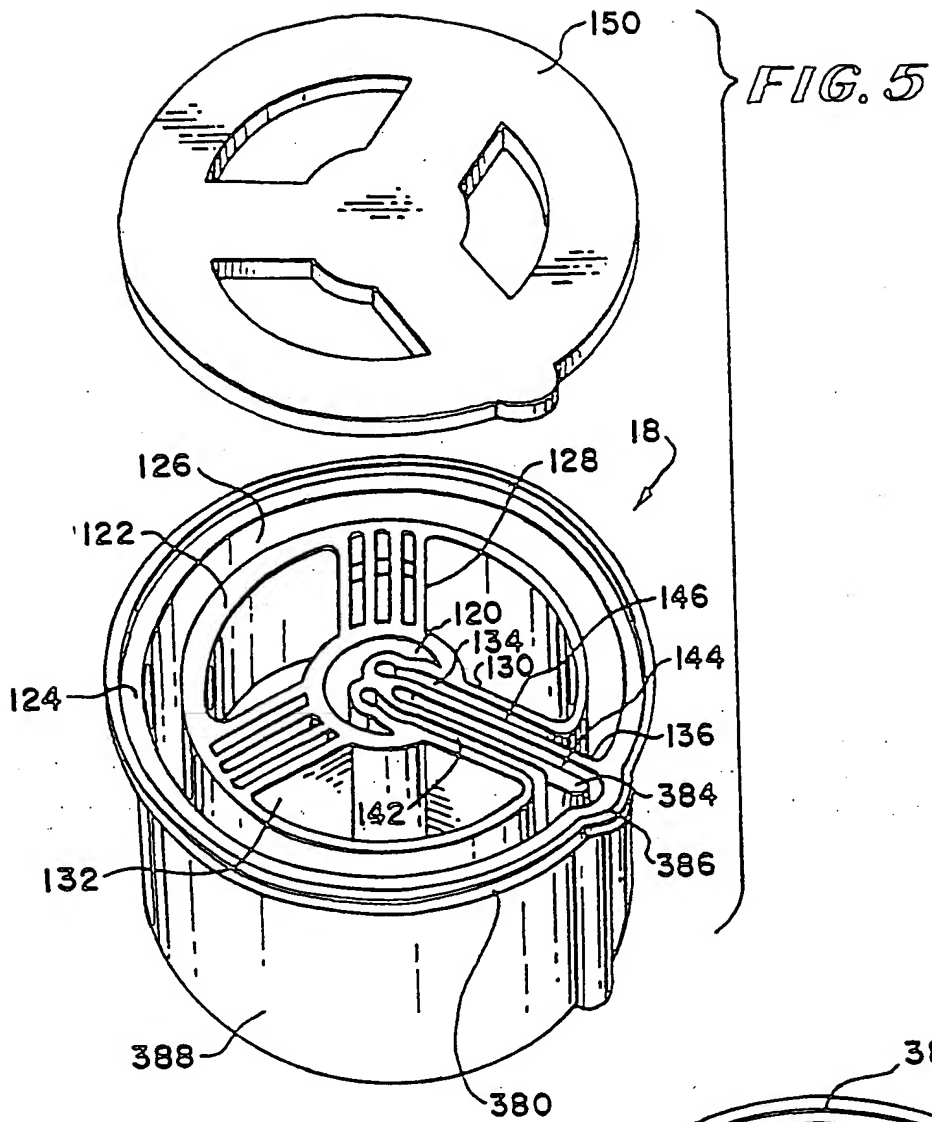
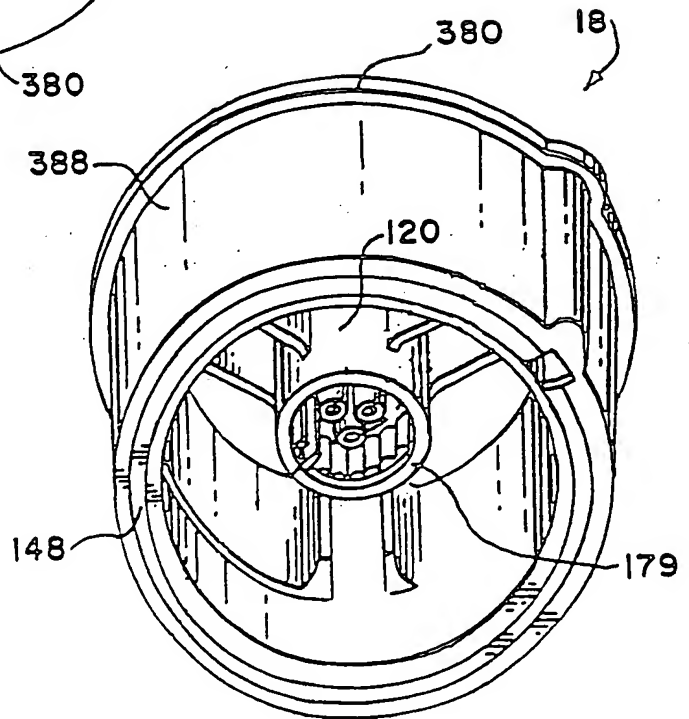


FIG. 6



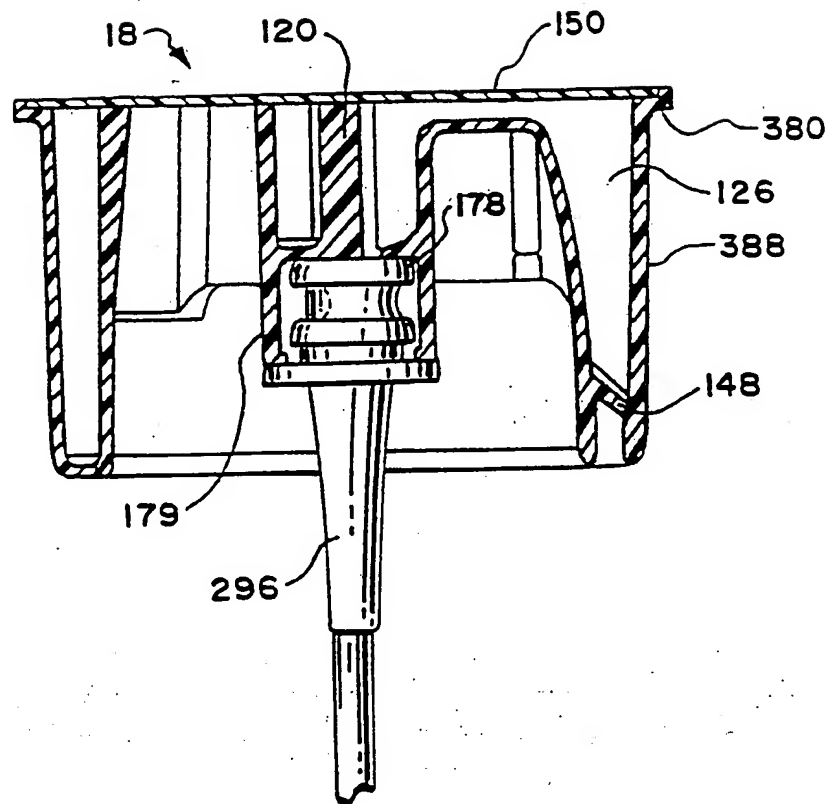
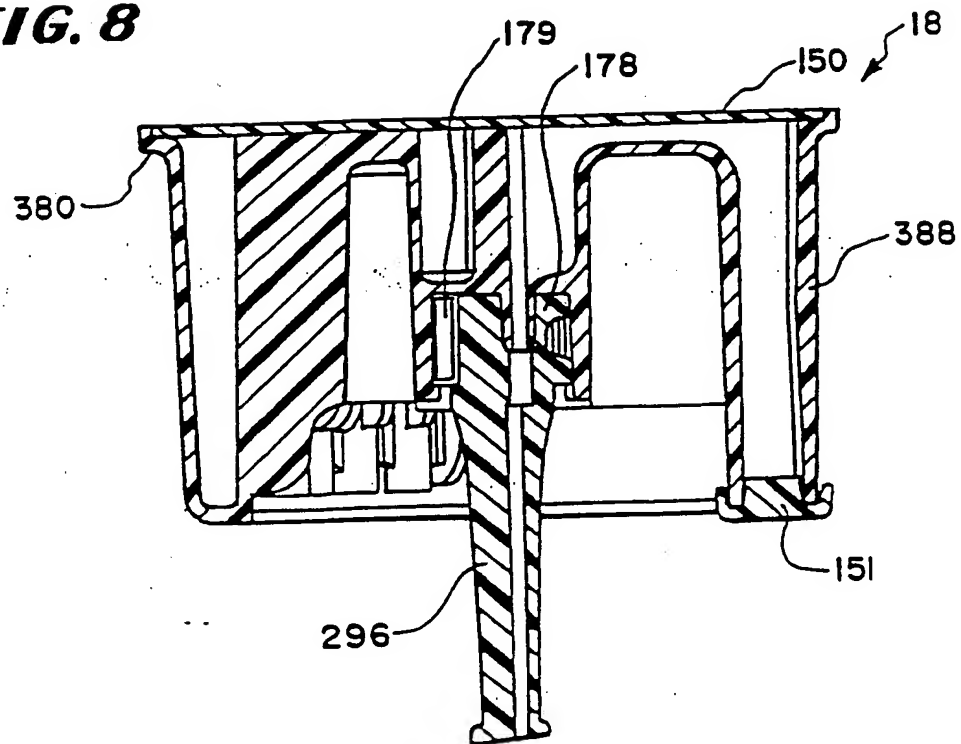
**FIG. 7****FIG. 8**

FIG. 9

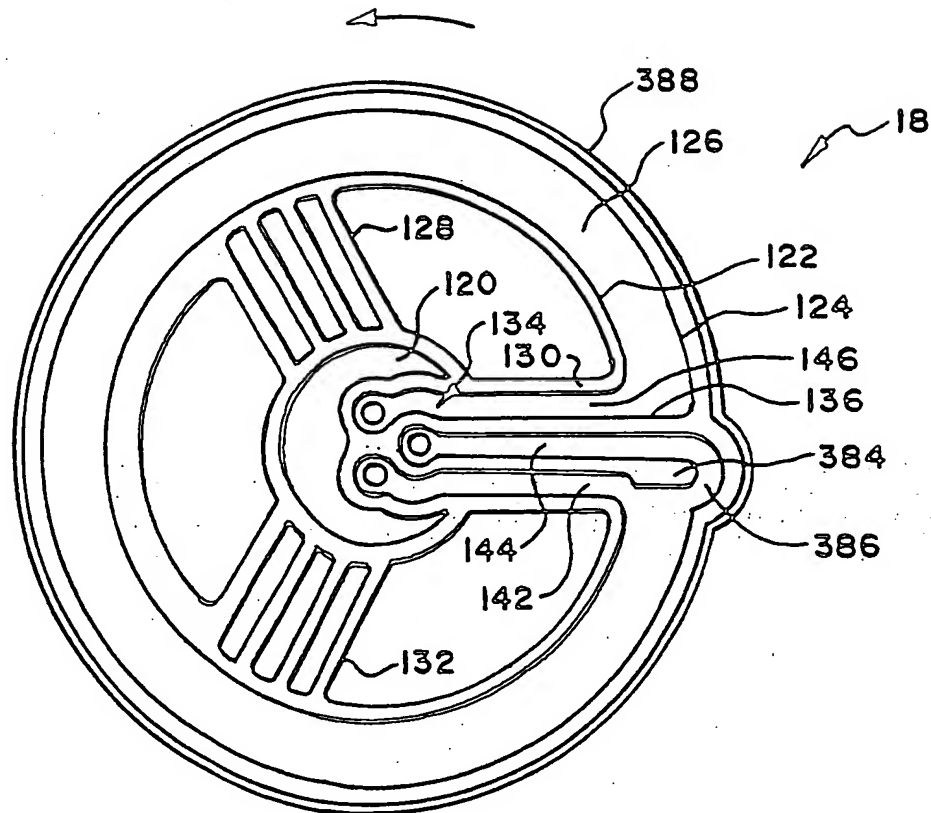
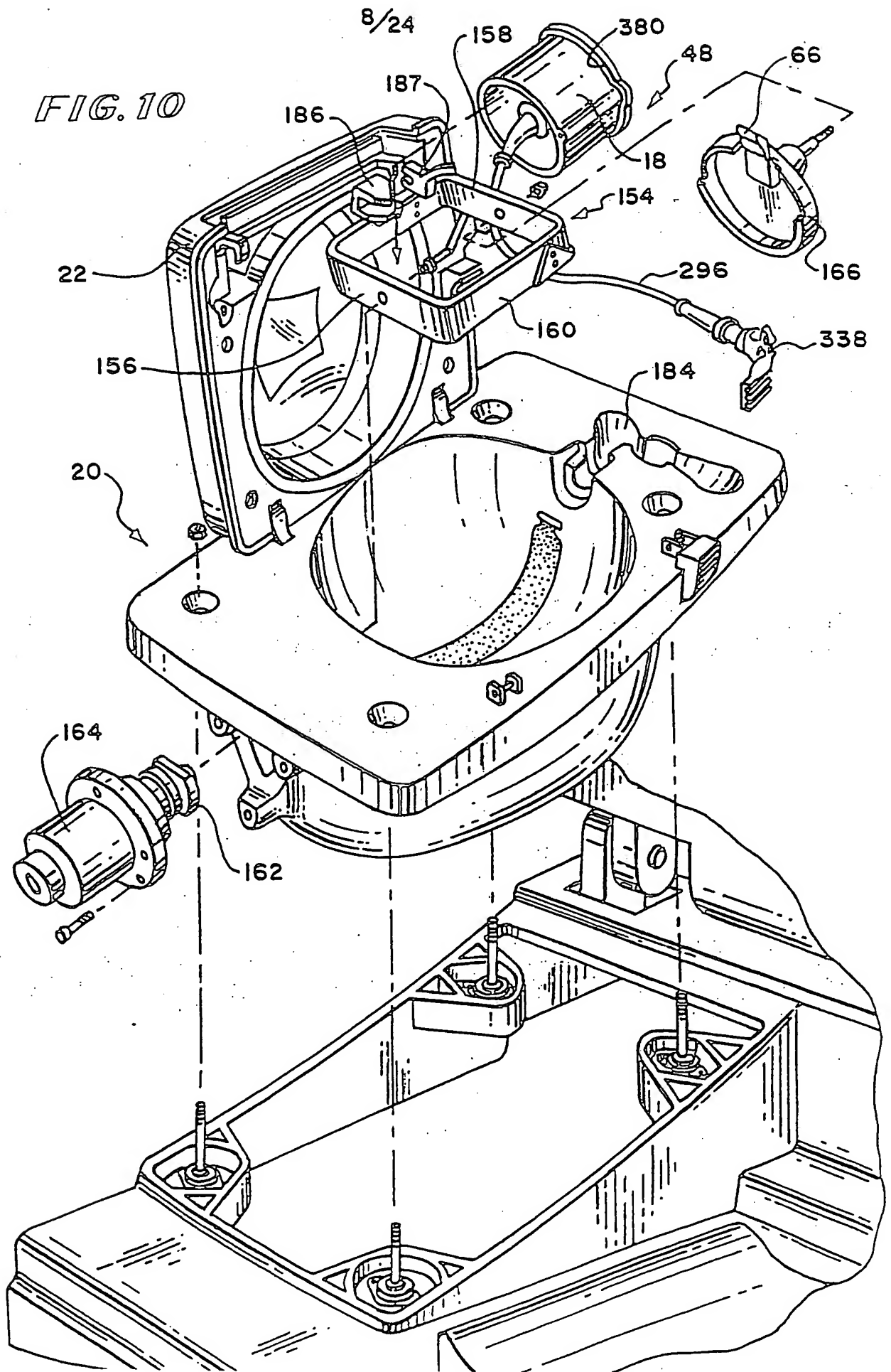
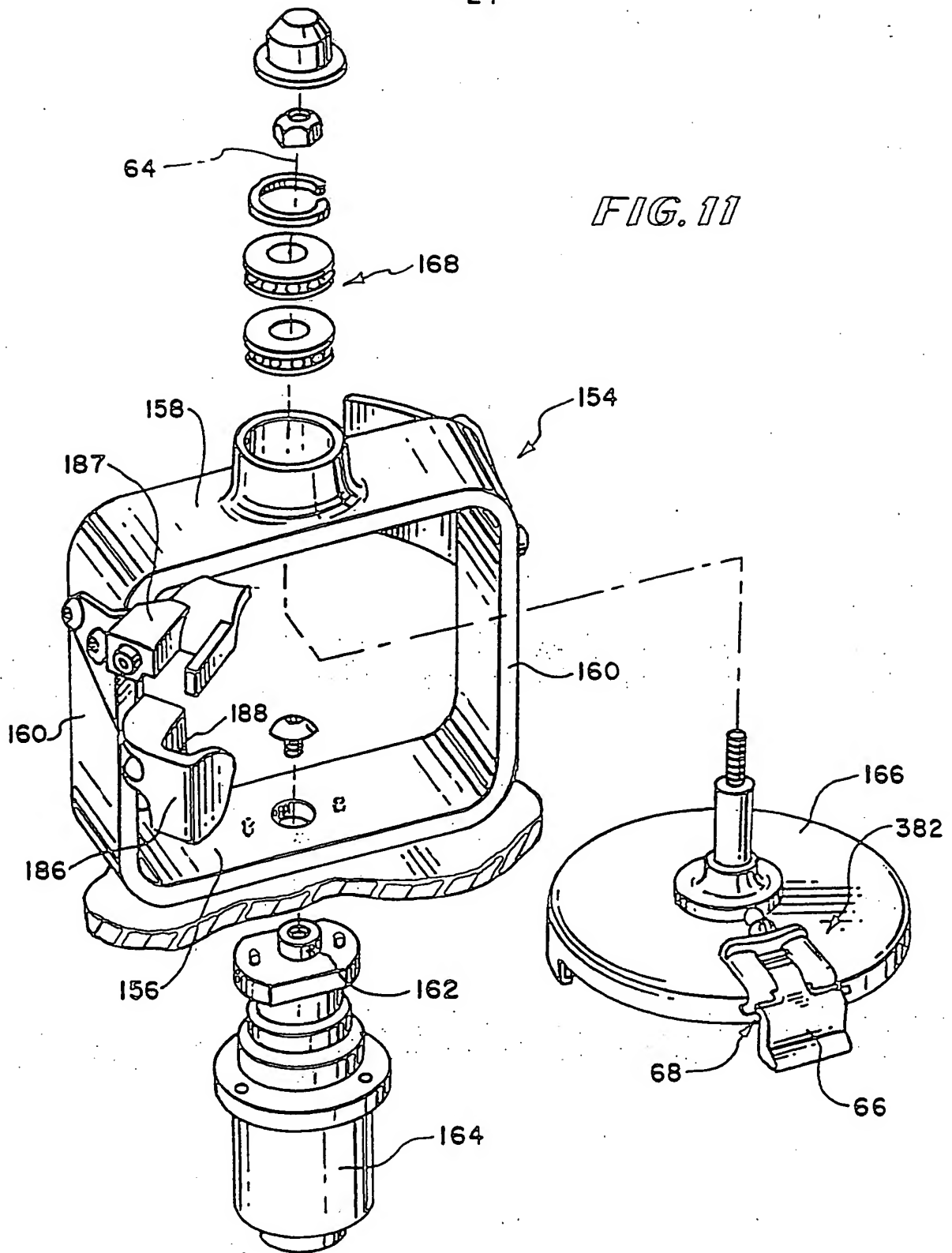




FIG. 10



9/24



10/24

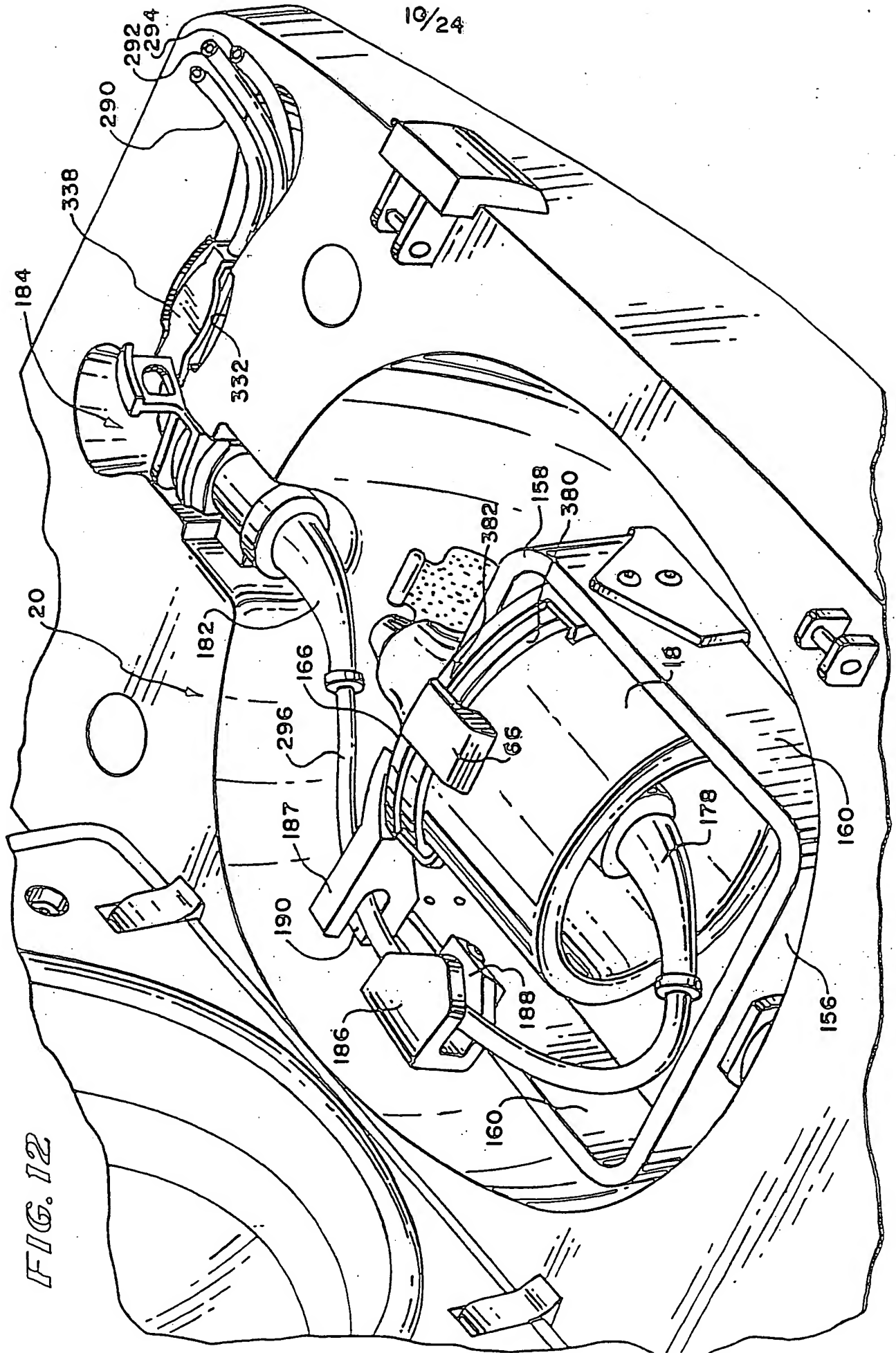
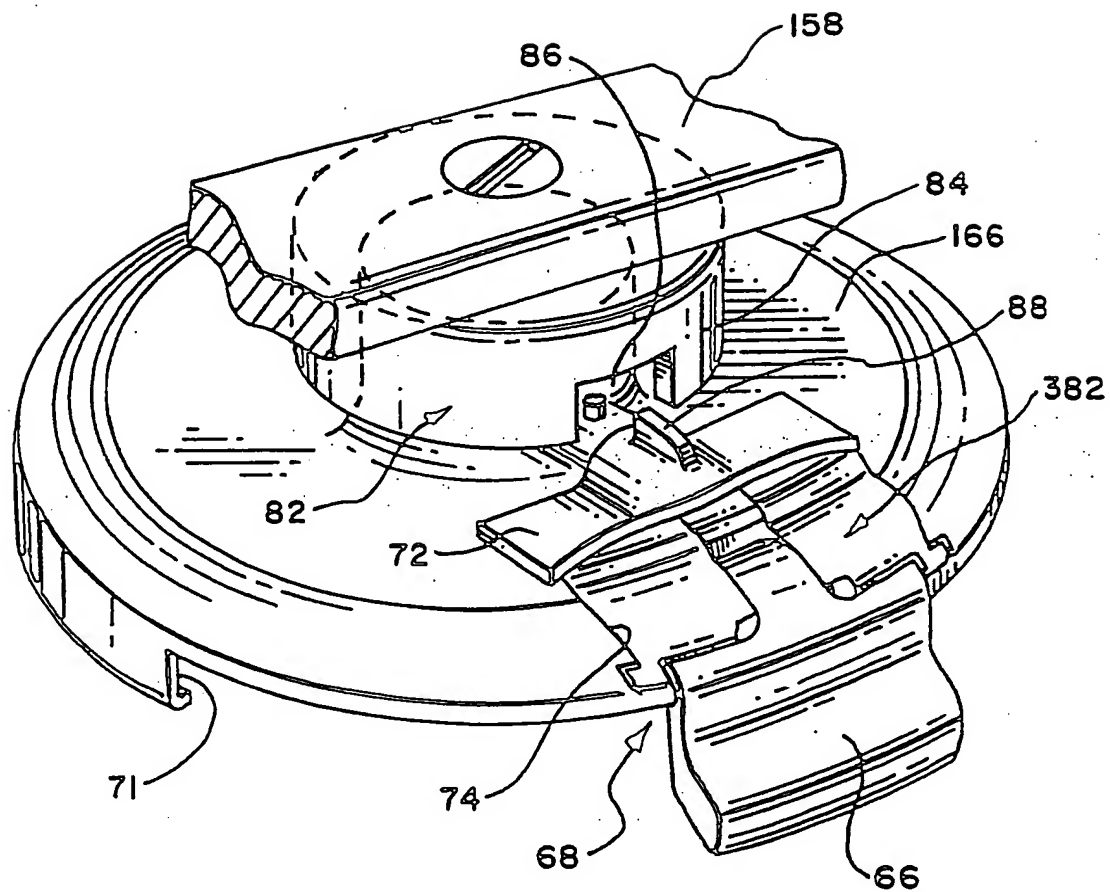
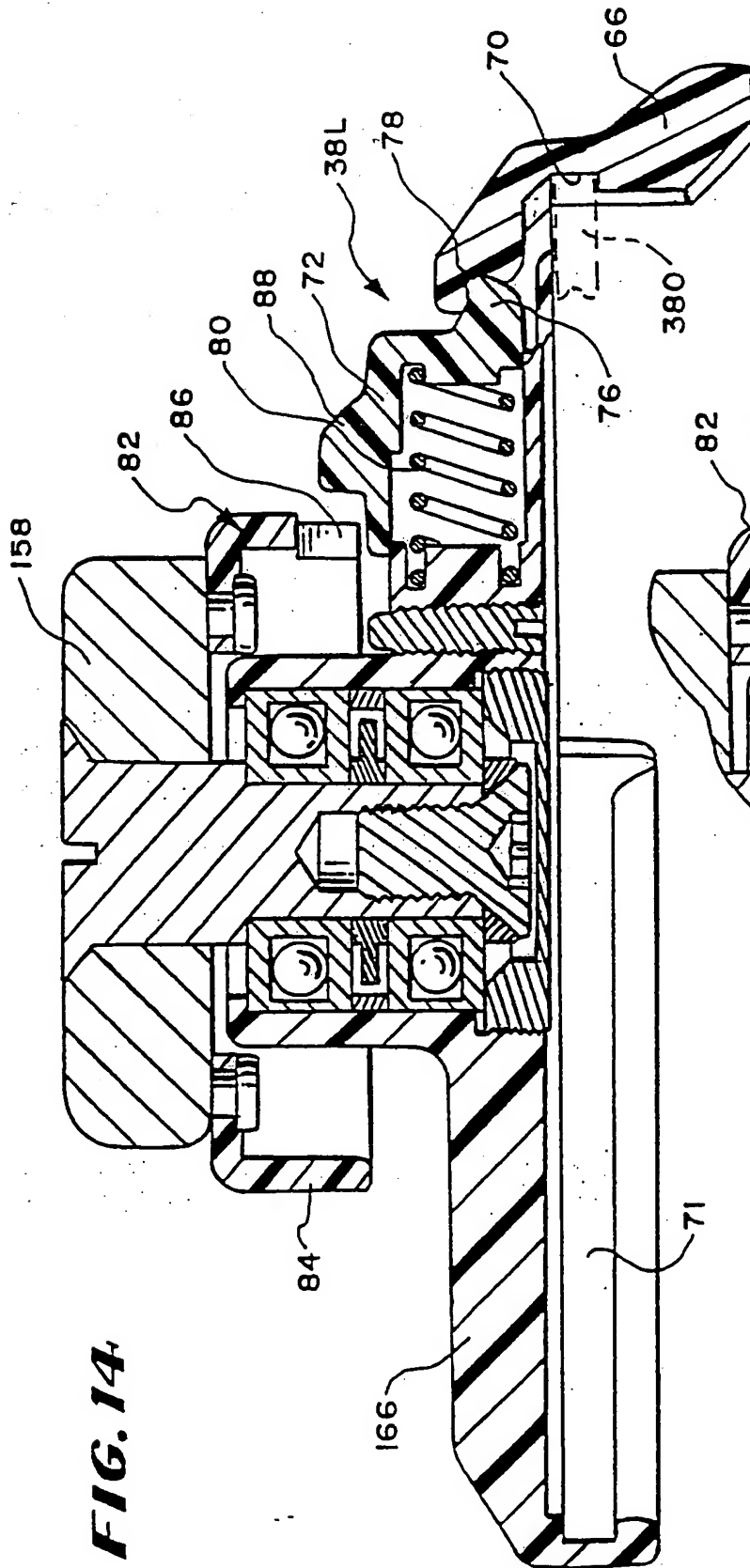


FIG. 12

FIG. 13



**FIG. 14**



**FIG. 15**

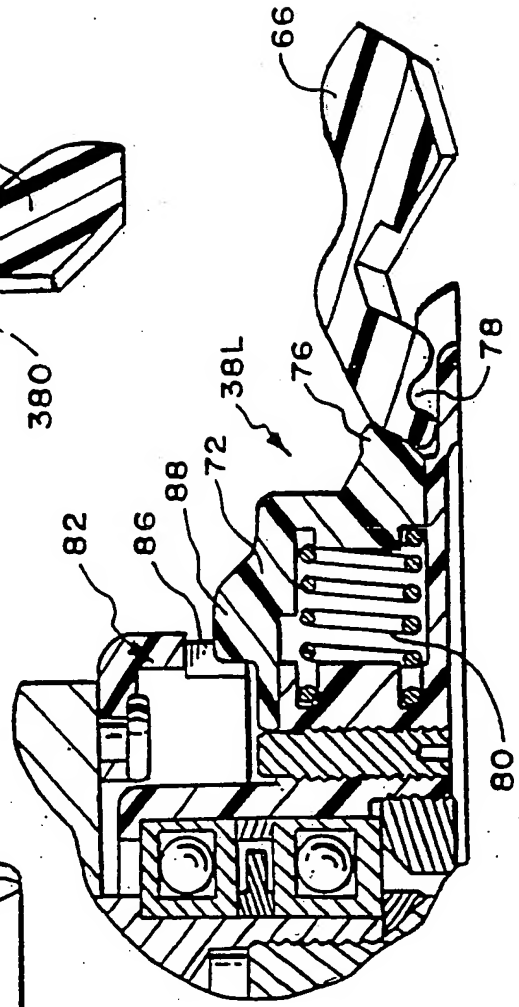
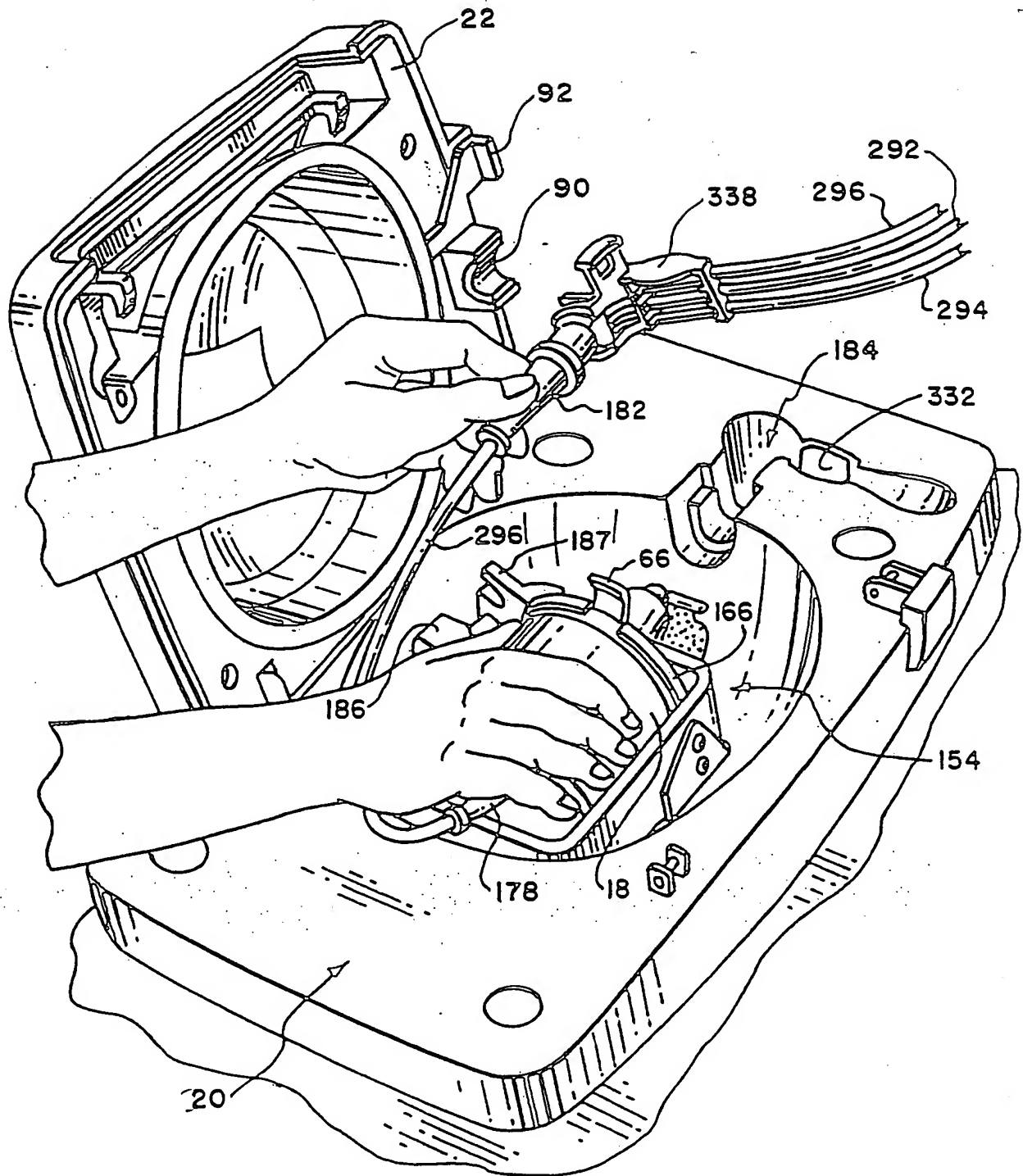


FIG. 16



**FIG. 17**

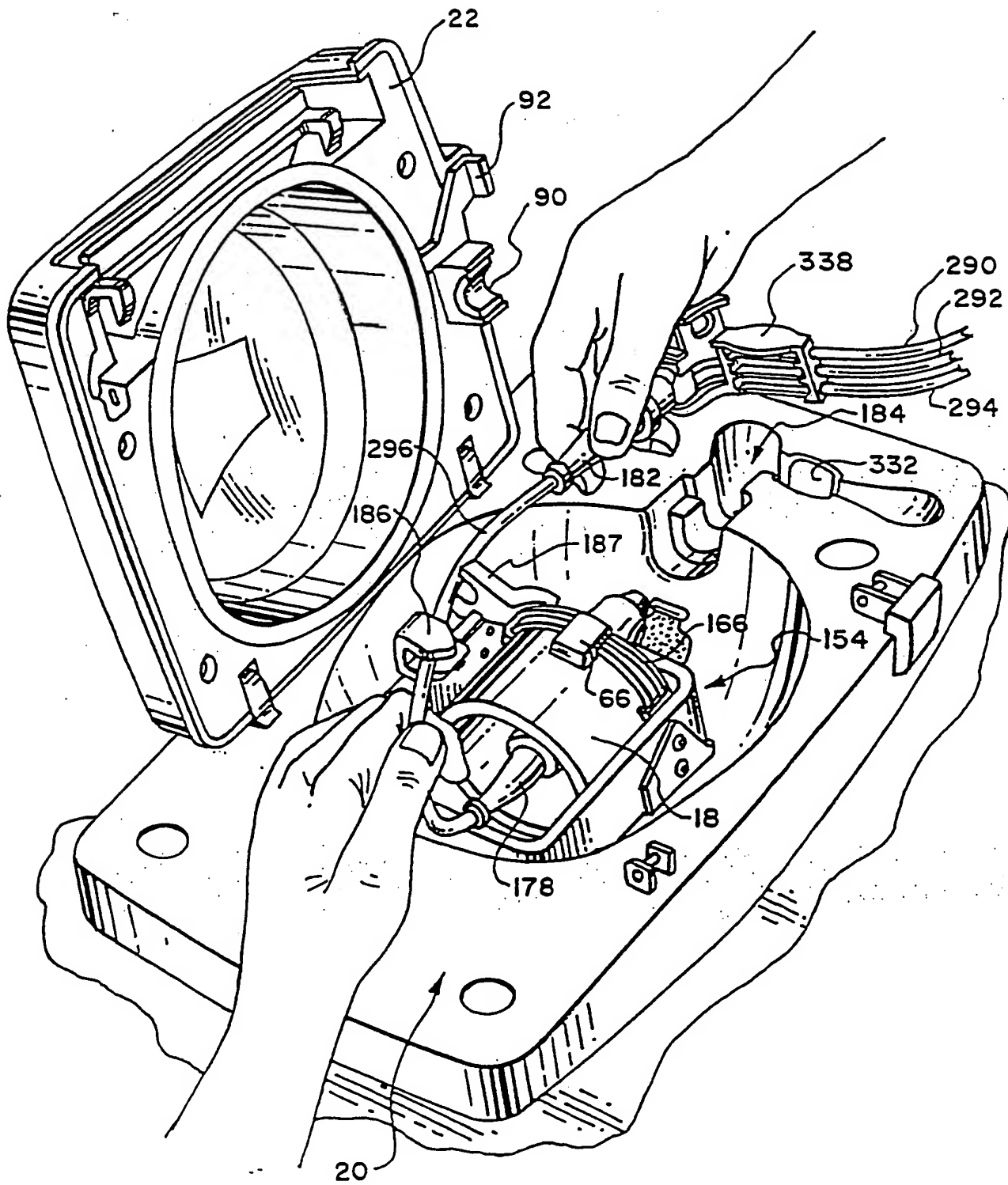
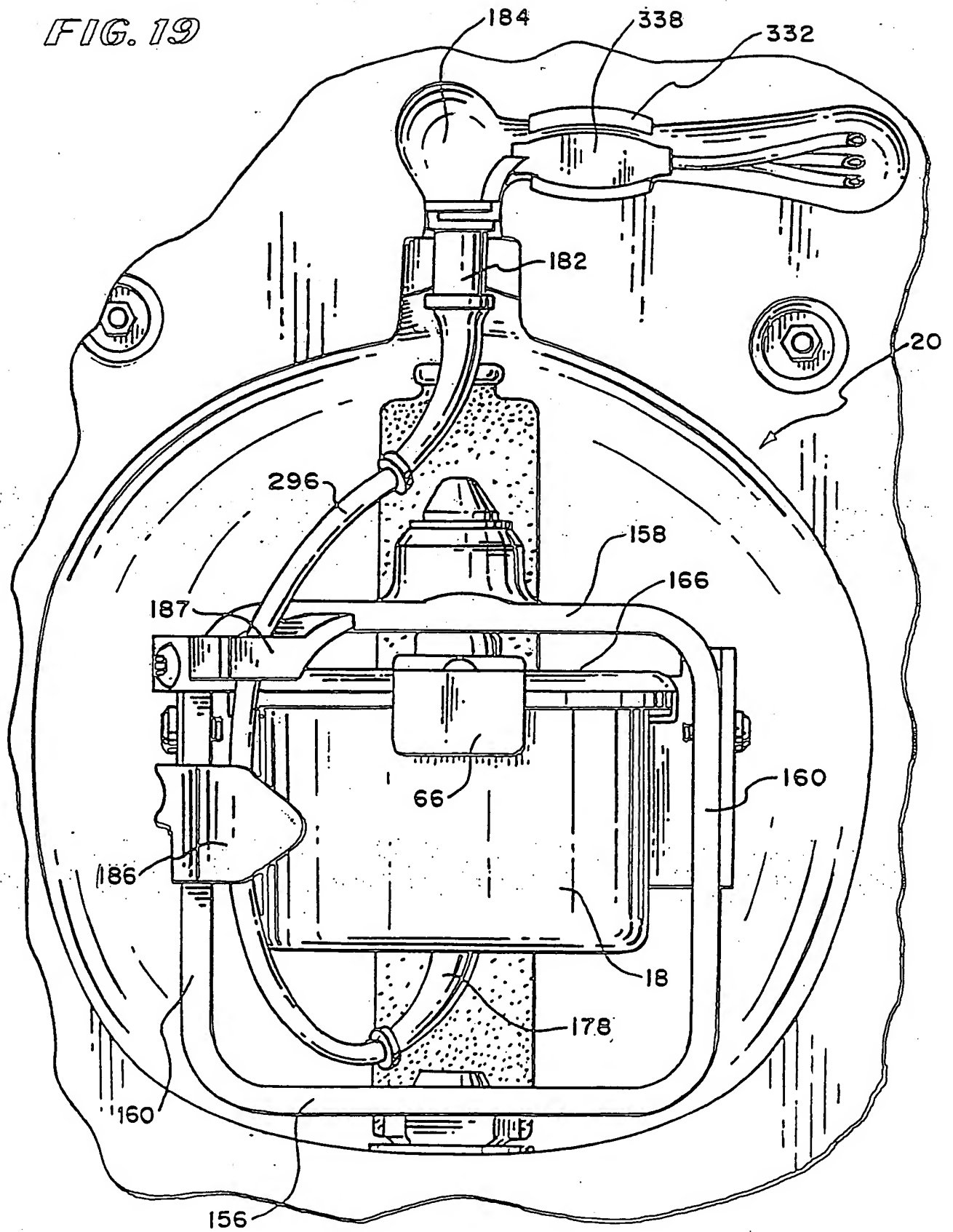
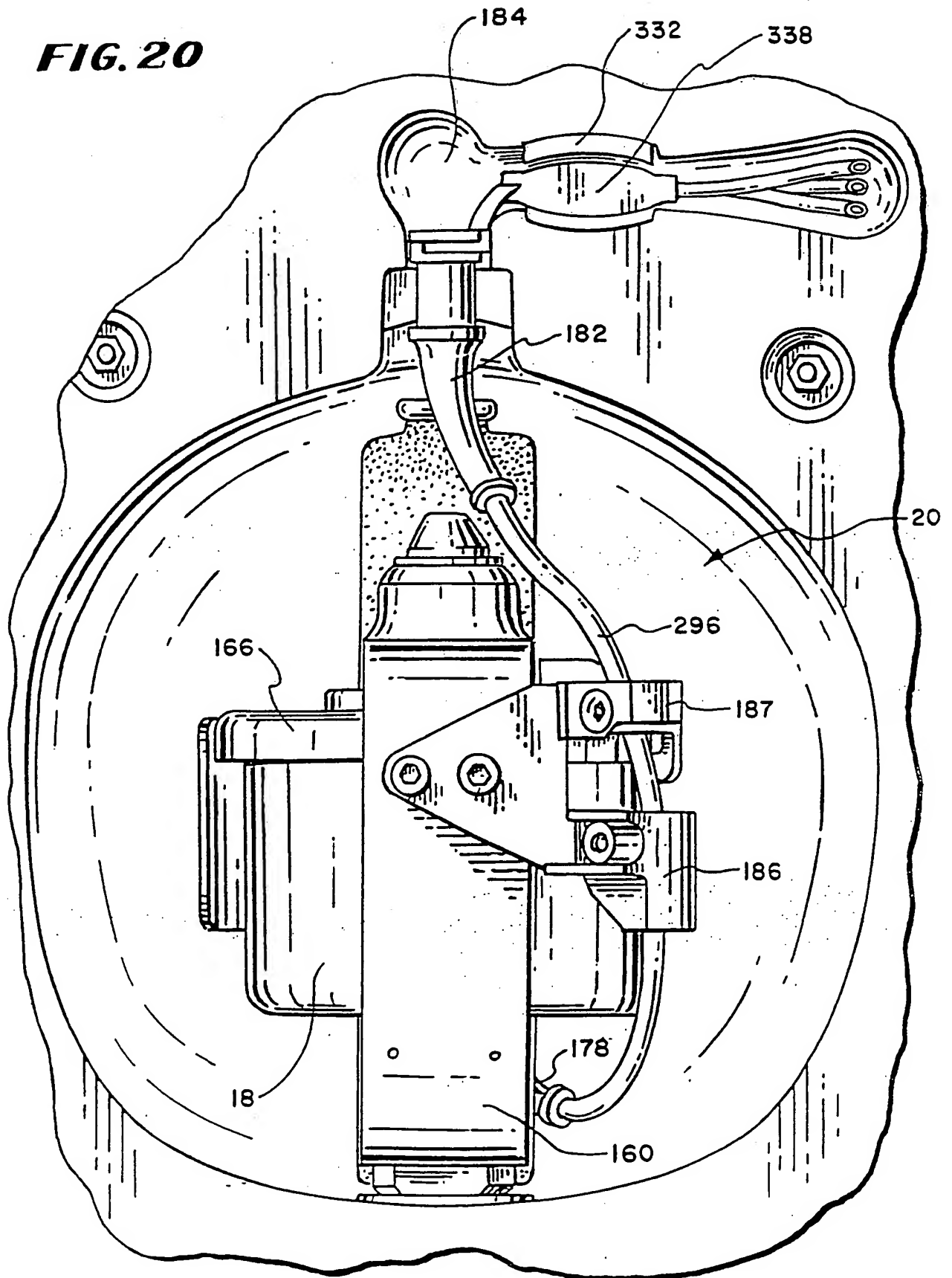






FIG. 19



**FIG. 20**

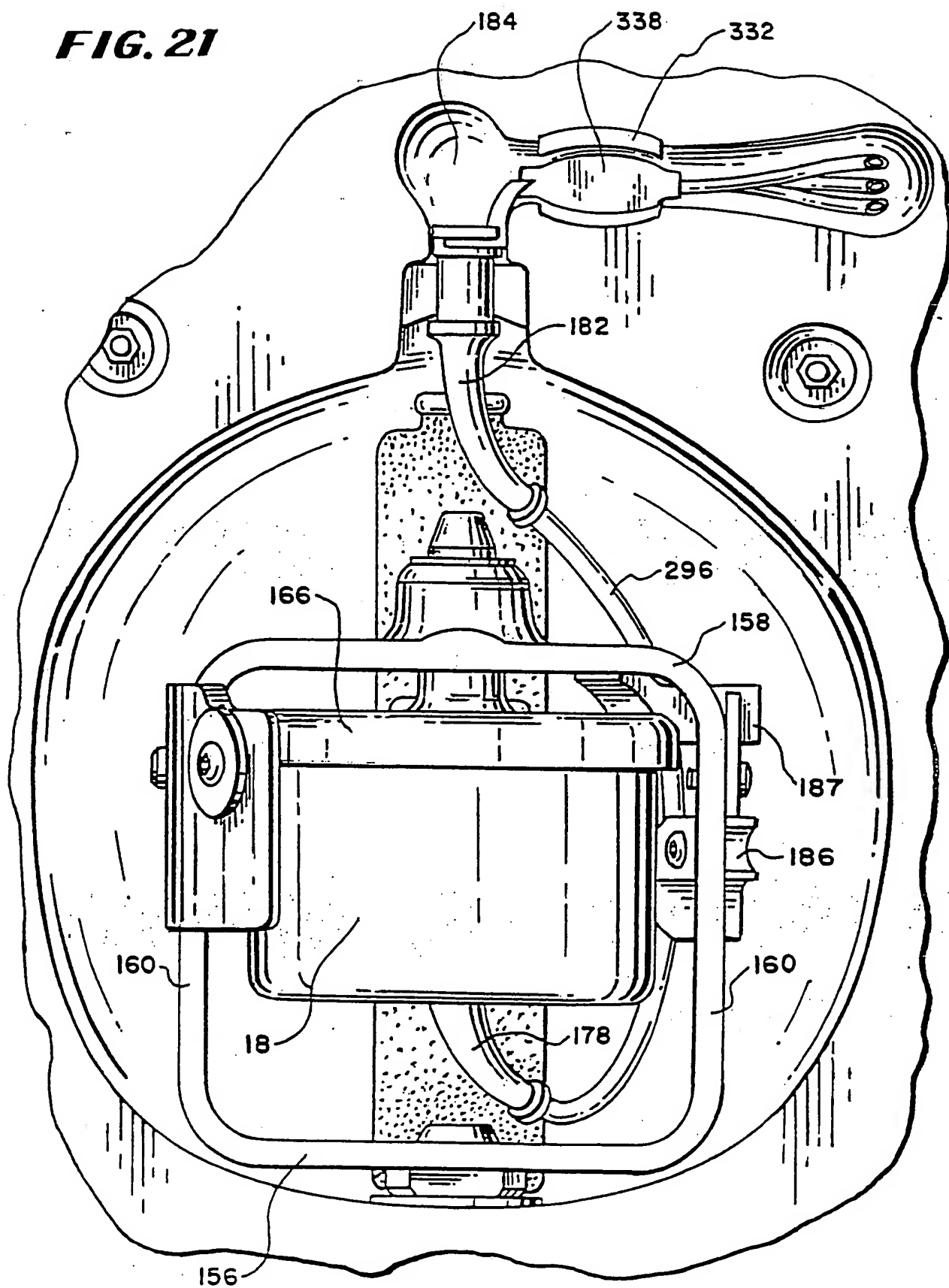
**FIG. 21**

FIG. 22

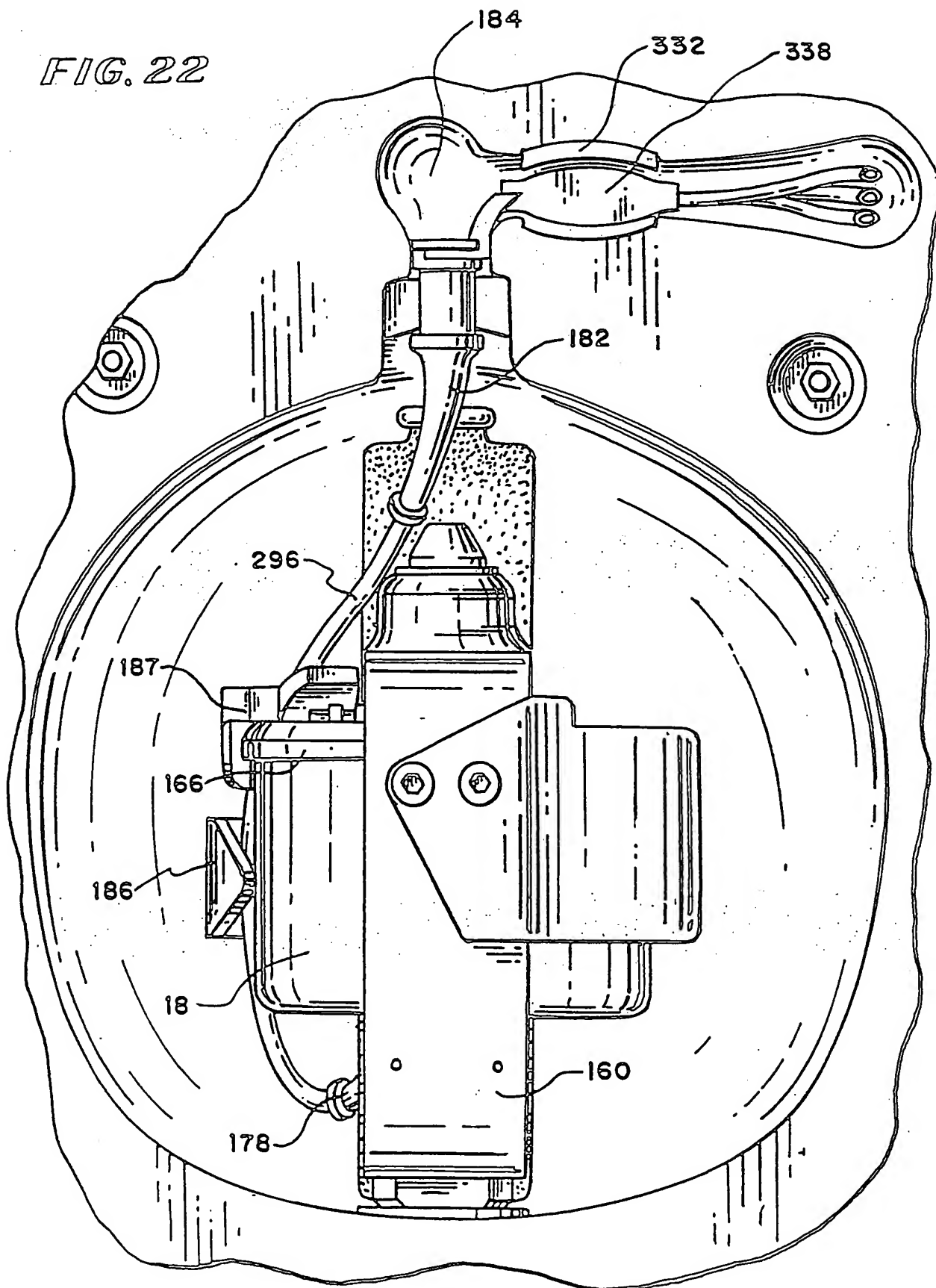
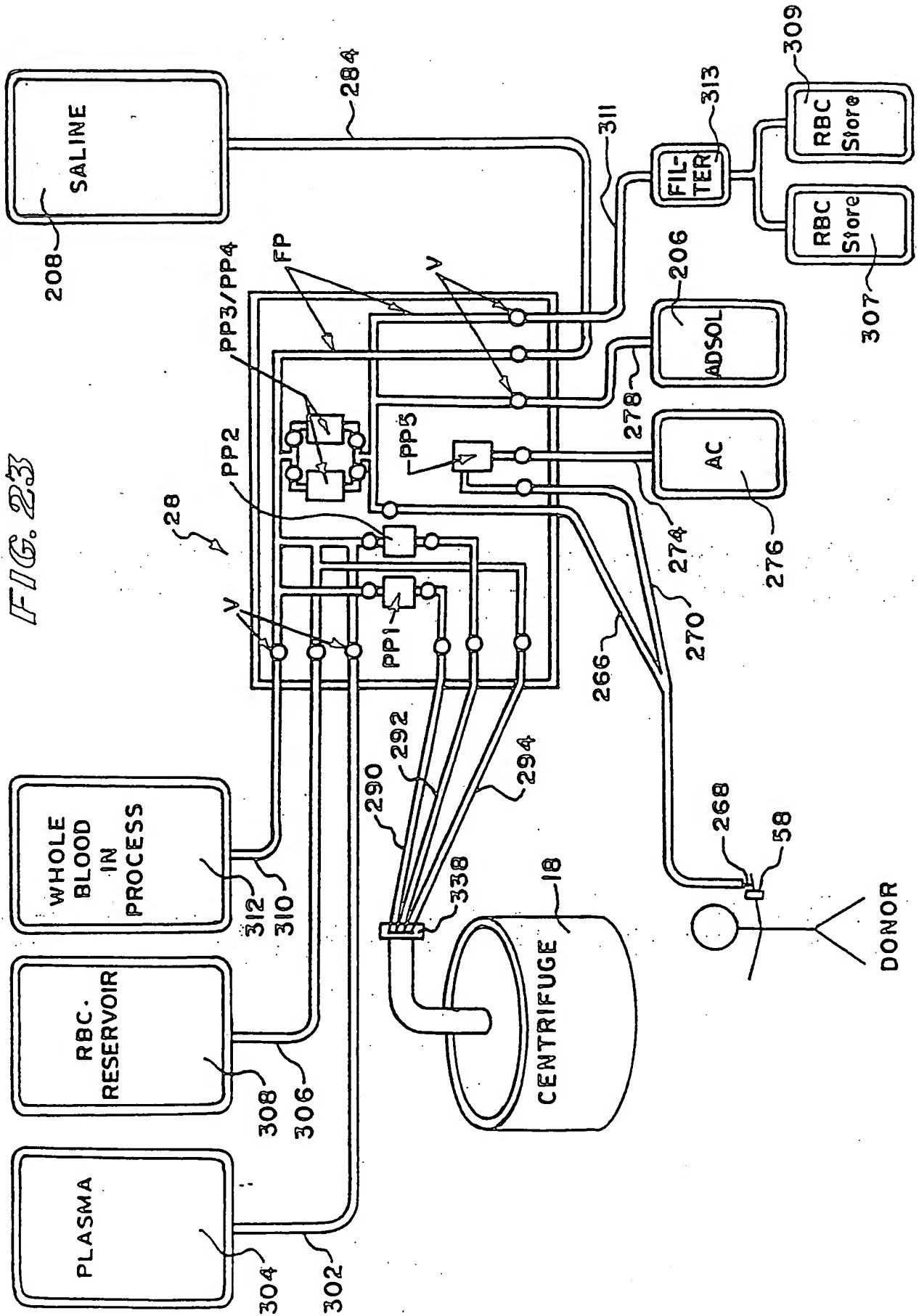


FIG. 23



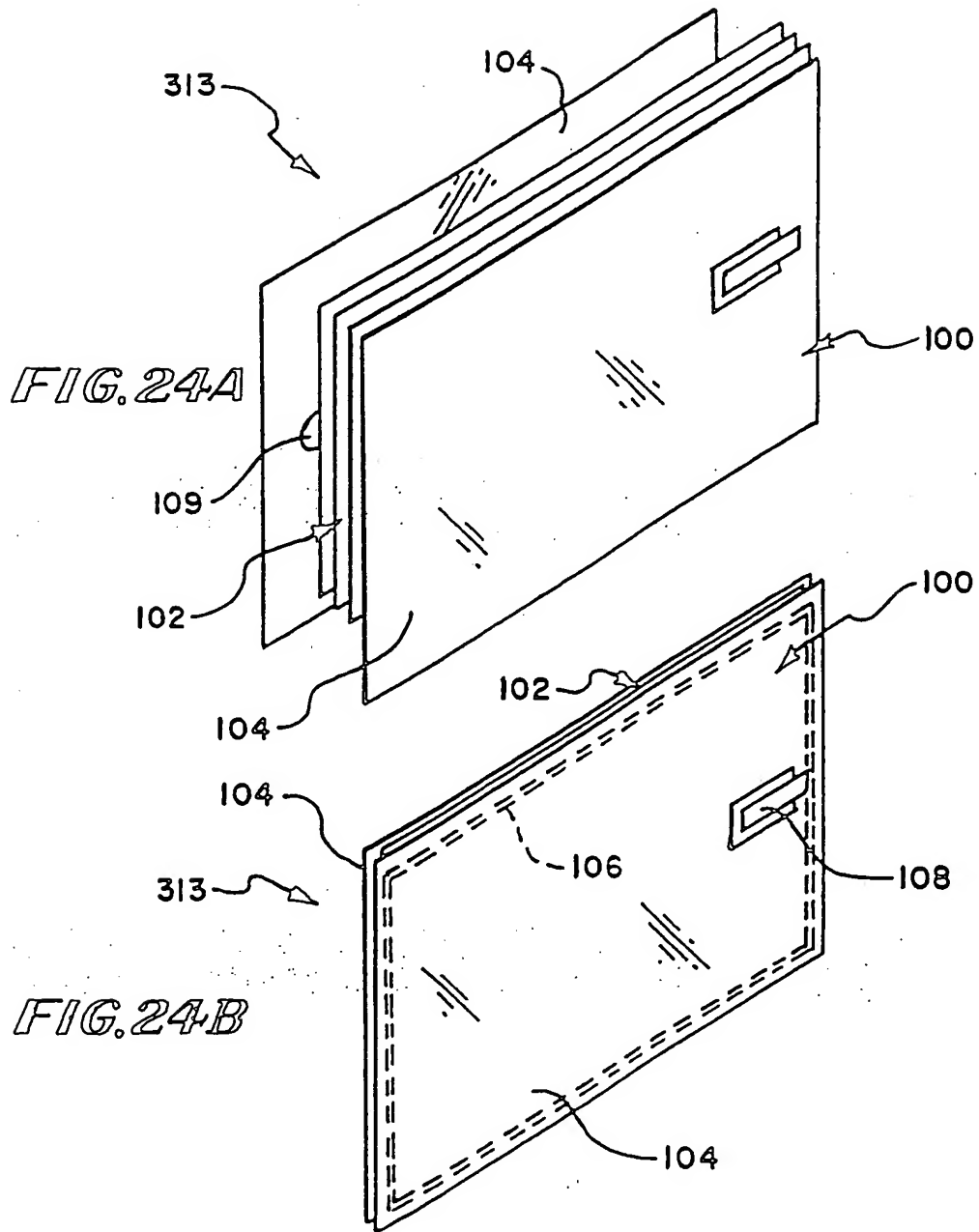


FIG. 25A

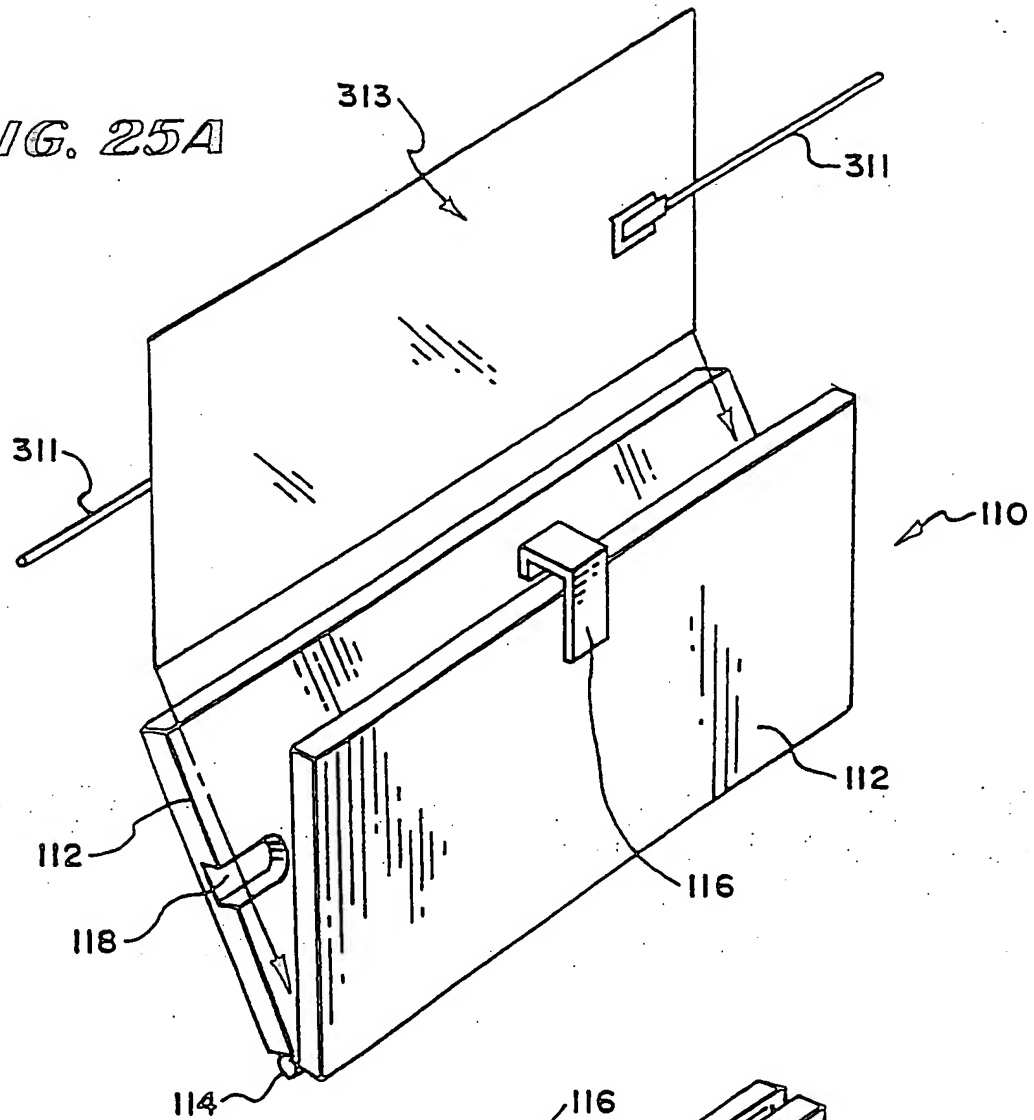


FIG. 25B

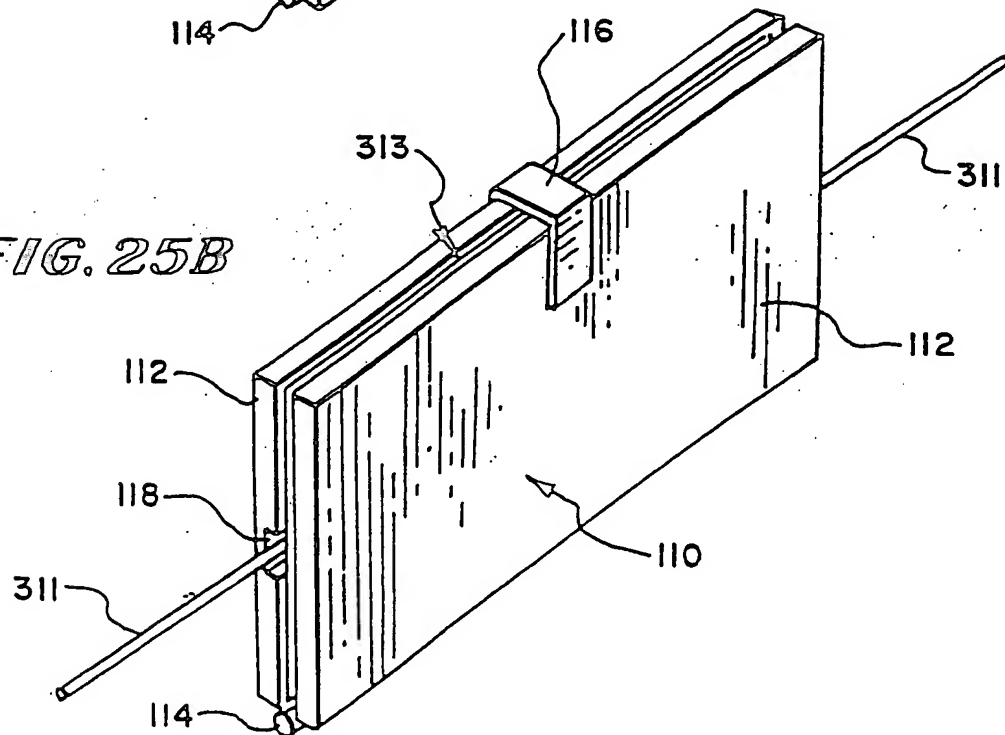
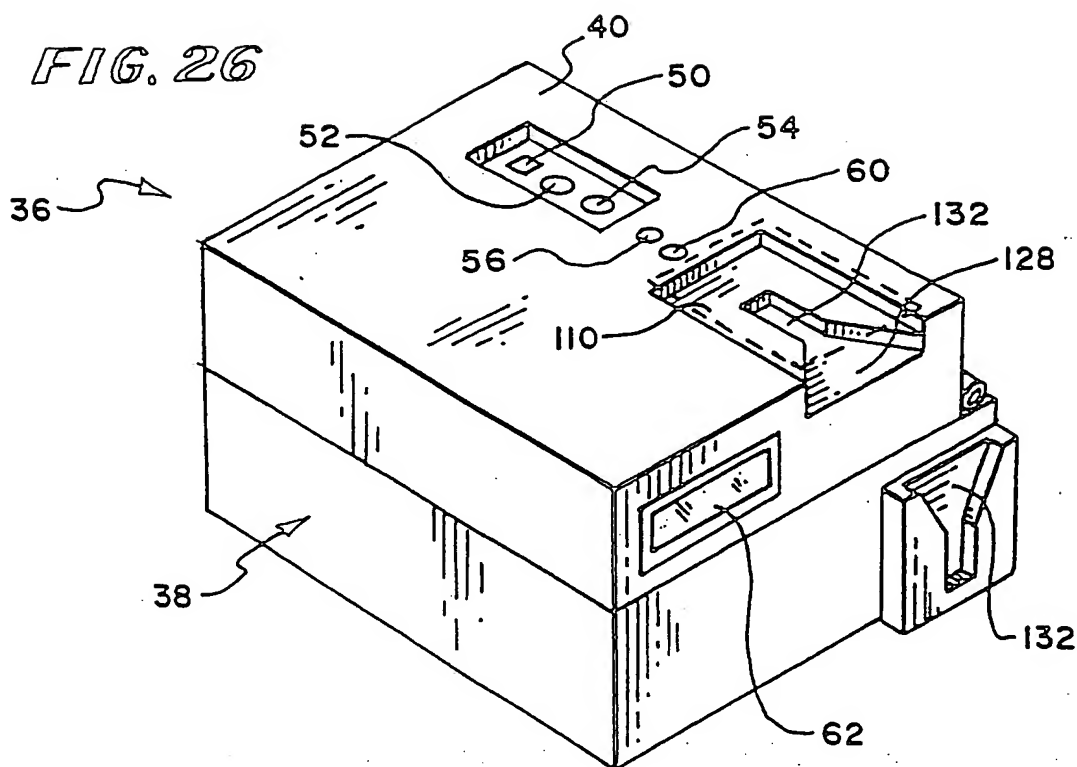


FIG. 26



FROM RED BLOOD  
CELL RESERVOIR 308

FIG. 27

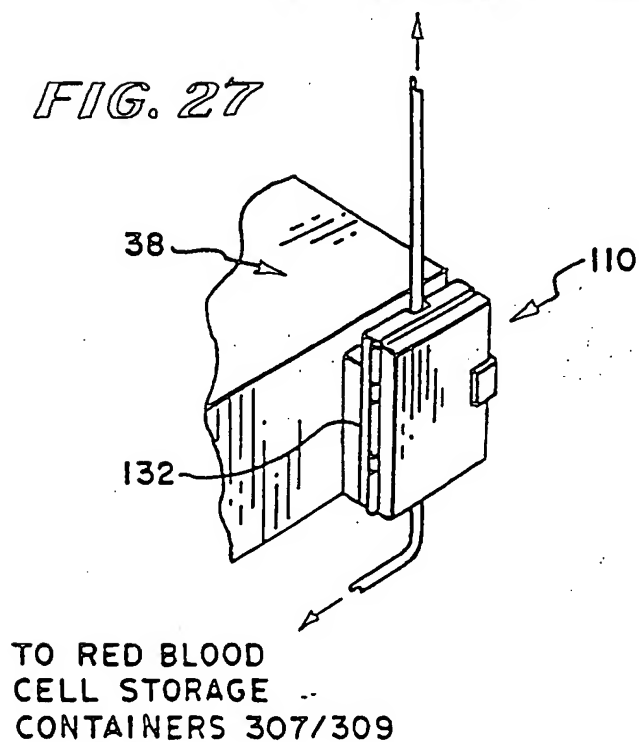
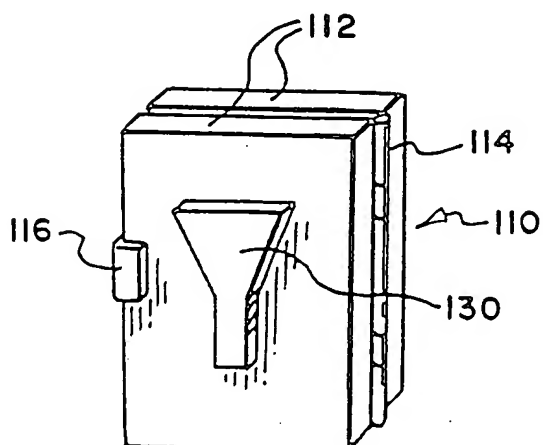


FIG. 28





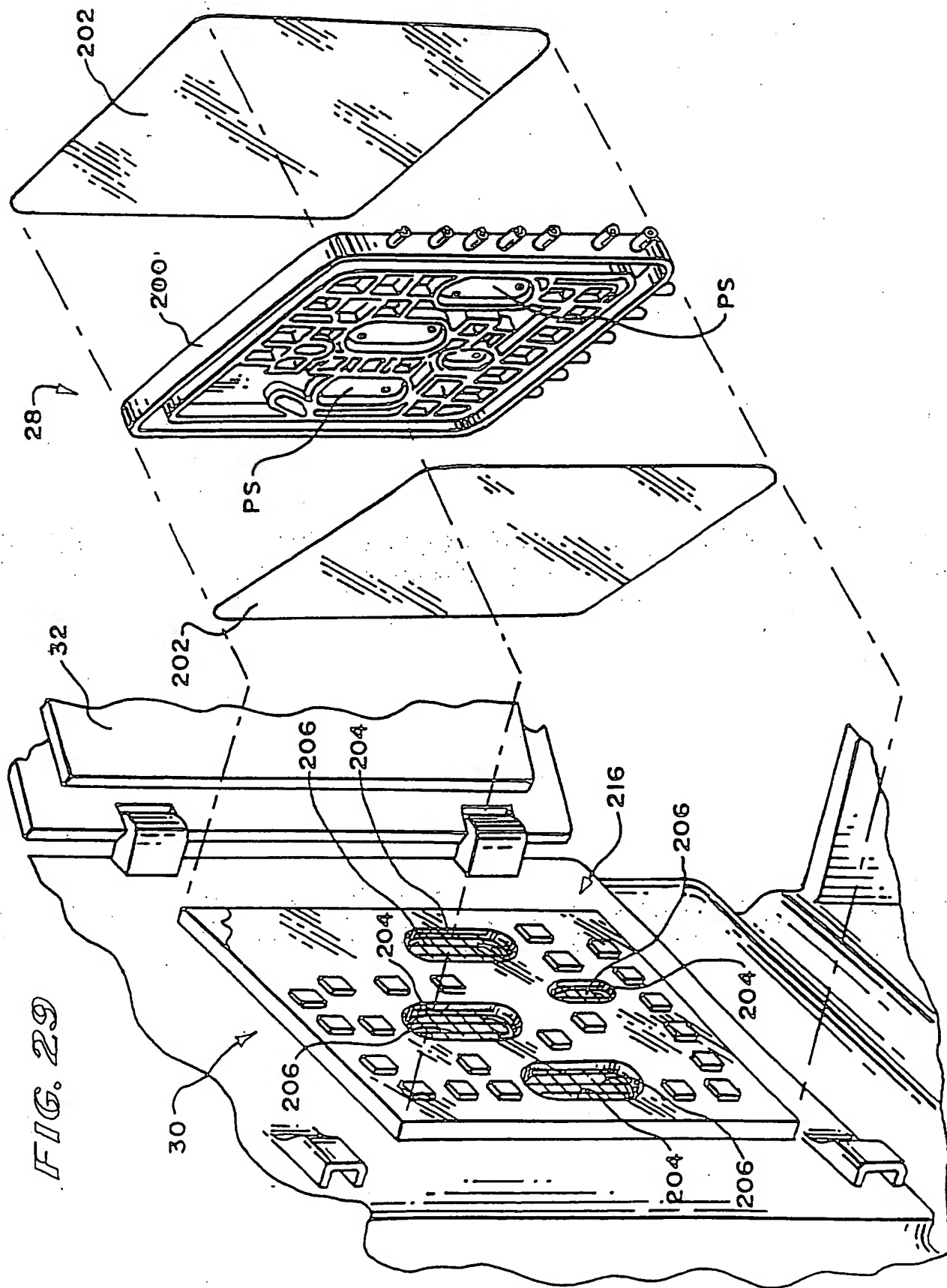


FIG. 29

Customer No.: 26308

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Please amend the application prior to the first office action as follows:

### AMENDMENT TO THE CLAIMS

1 (Original). A blood processing system comprising

a blood processing set including a source of blood cells, and a blood component collection flow channel coupled to the source of blood cells including a blood cell storage container and an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container, the in-line filter including a fibrous filter medium, first and second flexible housings, a unitary, continuous peripheral seal formed by application of pressure and radio-frequency heating in a single process to join the first and second flexible housings to each other, as well as join the fibrous filtration medium to the first and second flexible housings, and

a pump station adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter.

2 (Original). A blood processing system according to claim 1

further including a fixture to restrain expansion of the first and second filter housings as a result of pressure applied during operation of the pump station.

3 (Original). A blood processing system according to claim 2

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

4 (Original). A blood processing system according to claim 1

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

5 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the controller includes a function to derive a value reflecting volume of blood cells present in the blood cell storage container after passage through the filter as a percentage of volume of blood cells conveyed to the filter.

6 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the pump station includes a fluid pressure actuated pump and an actuator to apply fluid pressure to the pump.

7 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the blood cells comprise red blood cells.

8 (Original). A method of processing blood comprising using the blood processing system as defined in claim 1 or 2 or 3 or 4.

9 (New). In a method of filtering a liquid using a filter comprising a flexible housing having an inlet port and outlet port for the liquid and a sheet-like filter element for removing undesired components from the liquid, with the inlet port being separated from the outlet port by the filter element, a method characterized by maintaining the pressure at the outlet side of the filter at a positive pressure above atmospheric pressure by controlling a feed rate per unit time of a feed pump installed in an upstream flow channel of the filter.

10 (New). The method according to claim 9, wherein the filter does not comprise a spacer for securing a flow channel at the outlet side of the filter.

11 (New). The method according to claim 9 or claim 10, wherein the filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet side and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

12 (New). The method according to claim 9, wherein the liquid to be filtered is blood.

13 (New). The method according to claim 10, wherein the liquid to be filtered is blood.

14 (New). The method according to claim 11, wherein the liquid to be filtered is blood.

15 (New). The method according to claim 12, wherein the filter is used for removal of leukocytes.

16 (New). The method according to claim 13, wherein the filter is used for removal of leukocytes.

17 (New). The method according to claim 14, wherein the filter is used for removal of leukocytes.

18 (New). In a filtering system for a liquid comprising a filter comprising a flexible housing having an inlet port and outlet port for the liquid, a sheet-like filter element for removing undesired components from the liquid, with the liquid inlet port and the outlet port separated from each other by the filter element, an upstream side flow channel connected to the filter inlet port, a filtered liquid recovery bag, a downstream side flow channel connecting the filter outlet port with the recovery bag, and a feed pump installed in the upstream side flow channel, a filtering system wherein the feed

rate per unit time of a feed pump installed in an upstream flow channel of the filter can be controlled so that the pressure at the outlet side of the filter is maintained at positive pressure above atmospheric pressure.

19 (New). The system according to claim 18, comprising the filter without a spacer for securing a flow channel at the outlet side of the filter.

20 (New). The system according to a claim 18 or claim 19, wherein a filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet port and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

21 (New). The system according to claim 18, wherein the liquid to be filtered is blood.

22 (New). The system according to claim 19, wherein the liquid to be filtered is blood.

23 (New). The system according to claim 20, wherein the liquid to be filtered is blood.

24 (New). The system according to claim 21, wherein the filter is used for removal of leukocytes.

25 (New). The system according to claim 22, wherein the filter is used for removal of leukocytes.

26 (New). The system according to claim 23, wherein the filter is used for removal of leukocytes.

27 (New). A liquid filtering method using the system according to claim 18.

28 (New). A liquid filtering method using the system according to claim 19.

29 (New). A liquid filtering method using the system according to claim 20.

30 (New). A liquid filtering method using the system according to claim 21.

31 (New). A liquid filtering method using the system according to claim 22.

32 (New). A liquid filtering method using the system according to claim 23.

33 (New). A liquid filtering method using the system according to claim 24.

34 (New). A liquid filtering method using the system according to claim 25.

35 (New). A liquid filtering method using the system according to claim 26.

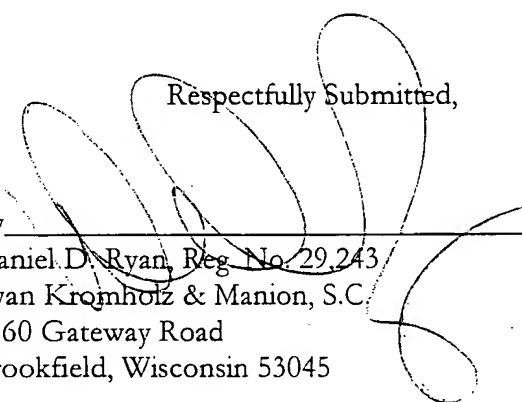
### REMARKS

New claims 9 to 35 have been added. The new claims are patterned after claims 11 to 16 and 29 to 35 of co-pending United States Patent Application Serial No. 10/474,805, filed April 2, 2002 (Foreign Priority: April 13, 2001), entitled "Liquid Filtering Method and Filtering System." With respect to these new claims 9 to 35, applicant concurrently files a document Suggesting an Interference Pursuant to 37 C.F.R. § 41.202(a), with companion Declarations.

Applicant notes that the instant application is a continuation of United States Patent Application Serial No. 09/976,833, filed October 13, 2001, now United States Patent No. 6,709,412.

A request for Correction of Inventorship also accompanies this Amendment, by the addition of co-inventors and Tom Westberg and Rohit Vishnoi. The submission of new claims 9 to 35 necessitated this request. The co-inventors of the subject matter defined in new claims 9 to 35 are Mark Vandlik, Tom Westberg, and Rohit Vishnoi.

Respectfully Submitted,

By   
Daniel D. Ryan, Reg. No. 29,243  
Ryan Kromholz & Manion, S.C.  
3360 Gateway Road  
Brookfield, Wisconsin 53045

Gary W. McFarron, Reg. No. 27,357  
David Lesht, Reg. No. 30,472  
Cook, Alex, McFarron, Manzo, Cummings & Mehler  
200 W. Adams St., Suite 2850  
Chicago, Illinois 60606

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308

Customer No.: 26308

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**Request for Correction of Inventorship**

**Pursuant to 37 C.F.R. §1.48(c)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant hereby requests, pursuant to 37 C.F.R. §1.48(c), correction of inventorship in the above identified case by the addition of joint inventors Tom Westberg and Rohit Vishnoi. The addition of inventors is necessitated by amendment of the claims to add subject matter not present in the claims at the time this case was filed.

As required by 37 C.F.R. §1.48(b), accompanying this Request are:

1. Statements from added inventors Tom Westberg and Rohit Vishnoi that their addition is necessitated by amendment of the claims and that the inventorship error occurred without any deceptive intent on his part (TAB 1).
2. An assignment, executed by the added inventors Tom Westberg and Rohit Vishnoi, with a Request for Recordation (TAB 2). The assignment of the originally inventors Mark R. Vandlik, Michael J. Kast, and Kelly B. Smith has been previously recorded in the parent application (Serial Number 09/976833, now US 6,709,412) in Reel/Frame 012582/0905.
3. The written consent of the assignee to the correction (TAB 3).
4. A Declaration by the actual inventors as required by 37 C.F.R. §1.63 (TAB 4). Originally-named inventor (and assignor) Kelly B. Smith cannot at the present time be reached for signature (she has moved and her exact whereabouts are not known), and a Petition under 37 C.F.R. § 1.183

(TAB 5) requesting a waiver of the requirement of 37 C.F.R. § 1.64 when as here, assignee has consented to the correction (see MPEP 201.03 (B)), accompanies this Petition for Correction.

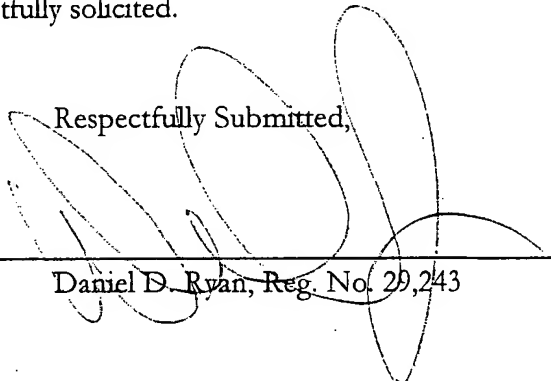
5. The processing fee as set forth in 37 C.F.R. §1.17(i).

A check payable in an amount to cover the requisite processing fee for this Request to Change Inventorship and Request for Recordation of Assignment is attached. You are authorized to charge any excess fees, or to credit overpayments, to Deposit Account No. 06-2360. A copy of this Request (without attachments) is attached for this purpose.

Approval of this Request is respectfully solicited.

Respectfully Submitted,

By

  
Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308



Customer No.: 26308

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

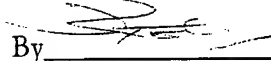
Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**STATEMENT OF ROHIT VISHNOI  
UNDER 37 C.F.R. 1.48(c) (2)**

I, Rohit Vishnoi, do understand that a petition has been made to change the inventorship in this patent by adding me as a joint inventor. I also understand that the addition was necessitated by amendment of the claims. The inventorship error occurred without any deceptive intention on my part.

I know that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the patent issued hereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Dated 7/28/04

By   
Rohit Vishnoi

Customer No.: 26308

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**STATEMENT OF TOM WESTBERG  
UNDER 37 C.F.R. 1.48(c) (2)**

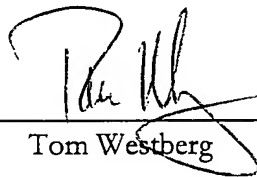
I, Tom Westberg, do understand that a petition has been made to change the inventorship in this patent by adding me as a joint inventor. I also understand that the addition was necessitated by amendment of the claims. The inventorship error occurred without any deceptive intention on my part.

I know that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the patent issued hereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Dated

7/25/05

By

  
Tom Westberg

RYAN KROMHOLZ & MANION, S.C.

17287

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DATE	DESCRIPTION	INVOICE #	AMOUNT	DEDUCTION	NET AMOUNT
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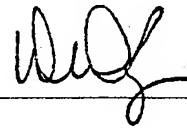
17287

RYAN KROMHOLZ & MANION, S.C.  
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MILWAUKEE, WI 53226-0618

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⑈017287⑈ ⑆075400575⑆ 0014 033 548⑈

## RECORDATION FORM COVER SHEET PATENTS ONLY

To the Director of the U.S. Patent and Trademark Office: Please record the attached documents or the new address(es) below.

**1. Name of conveying party(ies)/Execution Date(s):**

Tom Westberg  
Rohit Vishnoi

Execution Date(s) 7/25/2005 and 7/28/2005

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

**2. Name and address of receiving party(ies)**

Name: Baxter International Inc.

Internal Address: \_\_\_\_\_

Street Address: One Baxter Parkway

City: Deerfield

State: Illinois

Country: US Zip: 60015

Additional name(s) & address(es) attached? ☐ Yes ☒ No

**3. Nature of conveyance:**

- ☒ Assignment ☐ Merger  
☐ Security Agreement ☐ Change of Name  
☐ Government Interest Assignment  
☐ Executive Order 9424, Confirmatory License  
☐ Other \_\_\_\_\_

**4. Application or patent number(s):**

☐ This document is being filed together with a new application.

A. Patent Application No.(s)

10/765,498

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

**5. Name and address to whom correspondence concerning document should be mailed:**

Name: Daniel D. Ryan

Internal Address: Ryan Kromholz & Manion, S.C.

Street Address: P.O. Box 26618

City: Milwaukee

State: Wisconsin Zip: 53226

Phone Number: 262 783 1300

Fax Number: 262 783 1211

Email Address: \_\_\_\_\_

**6. Total number of applications and patents involved:**

**7. Total fee (37 CFR 1.21(h) & 3.41) \$ 40.00**

- ☐ Authorized to be charged by credit card  
☐ Authorized to be charged to deposit account  
☒ Enclosed  
☐ None required (government interest not affecting title)

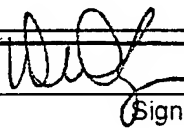
**8. Payment Information**

a. Credit Card Last 4 Numbers \_\_\_\_\_  
Expiration Date \_\_\_\_\_

b. Deposit Account Number 06-2360

Authorized User Name Daniel D. Ryan

**9. Signature:**



Signature

4 August 2005

Date

Daniel D. Ryan

Name of Person Signing

Total number of pages including cover sheet, attachments, and documents:

**Baxter**

**Assignment  
(Joint Inventors)**

Serial No. <sup>(1)</sup> 10/765,498

Filed <sup>(1)</sup> 01/26/2004

In consideration of ONE DOLLAR and other good and valuable considerations, the receipt and sufficiency whereof are hereby acknowledged, we hereby assign to BAXTER INTERNATIONAL INC. (hereinafter referred to as "assignee"), a corporation of Delaware, having a principal place of business at DEERFIELD, ILLINOIS, its successors, legal representatives and assigns, the entire right, title and interest throughout the world in our invention or improvements in

**(2) Blood Processing Systems and Methods that Employ an**

**In-Line Leukofilter Mounted in a Restraining Fixture**

and in the application for Letters Patent of the United States therefor, executed by each of us individually on the date(s) indicated below and any and all other United States applications and applications in any and all countries which we may file, either solely or jointly with others, on said invention or improvements, and in any and all Letters Patent of the United States or of any other country which may be obtained on any of the said applications, and in any reissue or extension thereof.

We hereby authorize and request the Commissioner of Patents to issue said Letters Patent to said BAXTER INTERNATIONAL INC.

We hereby authorize and request the attorneys of record in said application to insert in this assignment the date and serial number of said application when officially known.

We warrant ourselves to be the owners of the interest herein assigned and to have the right to make this assignment; and further warrant that there are no outstanding prior assignments, licenses, or other rights in the interest herein assigned.

For said considerations we hereby agree, upon the request and at the expense of said assignee, its successors, legal representatives and assigns, to execute any and all divisional, continuation, and renewal applications for said invention or improvements, and any necessary oath or supplemental oath or affidavit relating thereto, and any application for the reissue or extension of any Letters Patent that may be granted upon said application that said assignee, its successors, legal representatives and assigns may deem necessary or expedient, and for the said considerations we further agree, upon the request of said assignee, its successors, legal representatives and assigns, in the event of said application or any division thereof, or Letters Patent issued thereon, or any reissue or application for the reissue thereof becoming involved in interference, to cooperate to the best of our ability with said assignee, its successors, legal representatives and assigns in the matters of preparing and executing the preliminary statement and giving and producing evidence in support thereof. We further agree to perform, upon such request, any and all affirmative acts to obtain Letters Patent, and vest all rights therein hereby conveyed in the said assignee, its successors, legal representatives and assigns whereby said Letters Patent will be held and enjoyed by the said assignee, its successors, legal representatives and assigns to the end of the term for which said Letters Patent may be granted as fully and entirely as the same would have been held and enjoyed by us if this assignment and sale had not been made, and for the said considerations we hereby also assign to said assignee, its successors, legal representatives and assigns the entire right, title and interest in said invention or improvements for any and all foreign countries and the right of priority for patent and utility model applications in all countries arising under any applicable international convention for the protection of industrial property and/or any internal priority legislation of such countries, and we further agree upon the request of said assignee, its successors, legal representatives and assigns to execute any and all documents that shall be required to be executed in connection with any and all applications for foreign Letters Patent therefor, including the prosecution thereof, and to execute any and all documents necessary to invest title in said foreign applications and patents in said assignee.

WITNESS our hand and seal

Date 7/25/05 Signature [Signature]

<sup>(3)</sup> Typed Name: Tom Westberg

<sup>(4)</sup> State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by Tom Westberg  
Inventor

\_\_\_\_\_  
Notary Public

Date 7/28/05 Signature [Signature]

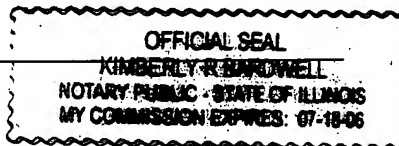
<sup>(3)</sup> Typed Name: Rohit Vishnoi

<sup>(4)</sup> State of Illinois, County of Lake

Signed before me on this 28 day of July, 2005

by Rohit Vishnoi  
Inventor

[Signature]  
Notary Public



Date \_\_\_\_\_ Signature \_\_\_\_\_

<sup>(3)</sup> Typed Name: \_\_\_\_\_

<sup>(4)</sup> State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by \_\_\_\_\_  
Inventor

Date \_\_\_\_\_ Signature \_\_\_\_\_

<sup>(3)</sup> Typed Name: \_\_\_\_\_

<sup>(4)</sup> State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by \_\_\_\_\_  
Inventor



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## Assignments on the Web &gt; Patent Query

## Patent Assignment Abstract of Title

**NOTE: Results display only for issued patents and published applications.  
For pending or abandoned applications please consult USPTO staff.**

## Total Assignments: 1

Patent #: 6709412 Issue Dt: 03/23/2004 Application #: 09976833 Filing Dt: 10/13/2001Publication #: US20020090319 Pub Dt: 07/11/2002

Inventors: Mark R. Vandlik, Michael J. Kast, Kelly B. Smith

Title: BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN IN-LINE LEUKOFILTER  
MOUNTED IN A RESTRAINING FIXTURE

## Assignment: 1

Reel/Frame: 012582/0905

Recorded: 02/12/2002

Pages: 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: VANDLIK, MARK R.

Exec Dt: 01/22/2002

KAST, MICHAEL J.

Exec Dt: 01/21/2002

SMITH, KELLY B.

Exec Dt: 01/21/2002

Assignee: BAXTER INTERNATIONAL INC

ONE BAXTER PARKWAY(2-2E)

DEERFIELD, ILLINOIS 60015

Correspondent: RYAN KROMHOLZ &amp; MANION, S.C.

DANIEL D. RYAN

P.O. BOX 26618

MILWAUKEE, WI 53226

Search Results as of: 08/02/2005 11:11 AM

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Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

CONSENT OF ASSIGNEE  
TO CHANGE OF INVENTORSHIP  
PURSUANT TO 37 C.F.R. §1.48(c)

Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015, the owner of 100% interest in this U.S. Patent Application by virtue of assignment, hereby assents to the correction of inventorship filed herewith, namely adding Tom Westberg and Rohit Vishnoi as co-inventors.

I state that I am authorized to act on behalf of the assignee.

In accordance with 37 C.F.R. 3.73, the assignee hereby certifies that the evidentiary documents with respect to ownership have been reviewed and that, to the best of the assignee's knowledge and belief, title is in the assignee seeking to take this action.

Dated August 3, 2005

By David P. Scharf *D.P.S.*

Typed Name David P. Scharf  
Assistant Corporate Secretary  
Title and Associate General Counsel

**COMBINED DECLARATION AND POWER OF ATTORNEY  
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION OR CIP)**

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type: (check one applicable item below)

- ☒ original  
☐ supplemental

Type of Application: (check one applicable item below)

- ☐ original  
☐ design

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.

- ☐ national stage of PCT

NOTE: If one of the following items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- ☐ divisional  
☒ continuation  
☐ continuation-in-part (CIP)

**INVENTORSHIP IDENTIFICATION**

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN  
IN-LINE LEUKOFILTER MOUNTED IN A RESTRAINING FIXTURE

**SPECIFICATION IDENTIFICATION**

the specification of which: (complete (a), (b) or (c))

- (a) ☐ is attached hereto.  
(b) ☒ was filed on 26 January 2004 as ☐ Serial No. 10/765,498  
or ☐ Express Mail No., as Serial No. not yet known \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

- (c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
filed on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_  
(if any).



# ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

☐ In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

## PRIORITY CLAIM (35 U.S.C. § 119)

A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(d) ☒ no such applications have been filed.  
(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>

B. CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application No.	Filing Date
_____	_____
_____	_____
_____	_____

## CLAIM FOR BENEFIT OF EARLIER US and/or PCT APPLICATION(S) UNDER 35 U.S.C. § 120

☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR US PRIORITY CLAIM

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

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NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. S 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Daniel D. Ryan (29,243)  
John M. Manion (38,957)  
Laura A. Dable (46,436)  
Patricia A. Limbach (50,295)  
Thomas J. Krumenacher (56,736)

Bradford R.L. Price (29,101)  
Joseph A. Kromholz (34,204)  
Daniel R. Johnson (46,204)  
Patrick J. Fleis (55,185)  
Melissa S. Hockersmith (56,960)

(check the following item, if applicable)

- [ ] Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

---

SEND CORRESPONDENCE TO

Bradford R.L. Price, Esquire  
BAXTER HEALTHCARE CORPORATION  
Senior Counsel  
One Baxter Parkway (DF3-2E)  
Deerfield, IL 60015

DIRECT TELEPHONE CALLS TO:  
(Name and telephone number)

Bradford R.L. Price  
(847) 948-4483

---

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

MARK (GIVEN NAME) R (MIDDLE INITIAL OR NAME) VANDLIK (FAMILY (OR LAST NAME))  
 Inventor's signature *Mark Vandlik*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS HAWTHORN WOODS, IL  
 Post Office Address 7712 GENEVA DRIVE 47 OLD LAKE ROAD  
GURNEE, ILLINOIS 60031 HAWTHORN WOODS, IL 60047 *EMV 7/29/05*

Full name of second joint inventor, if any

MICHAEL (GIVEN NAME) J (MIDDLE INITIAL OR NAME) KAST (FAMILY (OR LAST NAME))  
 Inventor's signature *Michael J Kast*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) EVANSTON, ILLINOIS  
 Post Office Address 1152 ASHLAND AVENUE  
EVANSTON, ILLINOIS 60202

Full name of third joint inventor, if any

KELLY (GIVEN NAME) B (MIDDLE INITIAL OR NAME) SMITH (FAMILY (OR LAST NAME))  
 Inventor's signature \_\_\_\_\_  
 Date \_\_\_\_\_ Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 506 CRYSTAL PLACE  
GURNEE, ILLINOIS 60031

Full name of fourth joint inventor, if any

TOM (GIVEN NAME) (MIDDLE INITIAL OR NAME) WESTBERG (FAMILY (OR LAST NAME))  
 Inventor's signature *Tom Westberg*  
 Date 7/25/2005 Country of Citizenship FI  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 17820 POND RIDGE CIRCLE  
GURNEE, ILLINOIS 60031

Full name of fifth joint inventor, if any

ROHIT (GIVEN NAME) (MIDDLE INITIAL OR NAME) VISHNOI (FAMILY (OR LAST NAME))  
 Inventor's signature *Rohit Vishnoi*  
 Date 7/25/2005 Country of Citizenship US  
 Residence (City, State/Country) DEERFIELD, ILLINOIS  
 Post Office Address 235 WILSON AVENUE  
DEERFIELD, ILLINOIS 60015

**ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR US PRIORITY CLAIM**

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120**

I hereby claim the benefit under Title 35, United States Code, S 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, S 112, I acknowledge the duty to disclose information that is material to the examination of this application, namely, information where there is substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:**

Status  
(CHECK ONE)

U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Abandoned
1. 09/976,833	10/13/2001	X		
2. 09/389,504	09/03/1999			X
3. _____	_____			

**PCT APPLICATIONS DESIGNATING THE U.S.**

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NOS. ASSIGNED (if any)
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

**35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS**

**DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY APPLICATION  
CLAIMED UNDER 35 USC 119**

	Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

CHECK PROPER BOX. 3) FOR ANY OF THE FOLLOWING ADD. PAGE(S) WHICH  
FORM A PART OF THIS DECLARATION

- ☐ Signature for sixth and subsequent joint inventors.

\* \* \*

- ☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor.

\* \* \*

- ☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47.

\* \* \*

- ☒ Added page to combined declaration and power of attorney for US Priority Claim

\* \* \*

- ☐ Authorization of attorney(s) to accept and follow instructions from representative

\* \* \*

*(If no further pages form a part of this declaration then end this declaration with this page and check the following item:)*

- ☐ This declaration ends with this page.

			CHECK		
DATE	DESCRIPTION	INVOICE #	AMOUNT	DEDUCTION	NET AMOUNT
Commissioner for Patents					
08/04/05	F-5489 CIP 2 CON Petition 37				
	CFR 1.183		130.00		130.00

CHECK DATE	CONTROL NUMBER	TOTALS ▶	Gross:	Ded:	Net:
08/04/05	17289		130.00	0.00	130.00

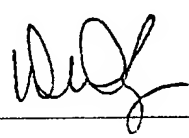
RYAN KROMHOLZ & MANION, S.C.  
POST OFFICE BOX 26618  
MILWAUKEE, WI 53226-0618

ASSOCIATED BANK  
79-57-759

DATE	CHECK	AMOUNT
08/04/05	****	\$130.00

PAY  
TO THE  
ORDER  
OF: Commissioner for Patents

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⑈017289⑈ ⑆075900575⑆ 0014 033 548⑈

Details on back.  
Security Features Included.

Customer No.: 26308

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**Petition Pursuant to 37 C.F.R. §1.183**

**Requesting Waiver of Requirement of 37 C.F.R. § 1.64**

**That an Original Inventor (Kelly B. Smith) Execute New Oath or Declaration**

**When New Inventors Are Added With Assignee's Consent**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant has requested, pursuant to 37 C.F.R. §1.48(c), a correction of inventorship in the above identified case by the addition of joint inventors Tom Westberg and Rohit Vishnoi. The addition of inventors is necessitated by amendment of the claims to add subject matter not present in the claims at the time this case was filed. Statements under 37 C.F.R. §1.48(c)(2); assignments; and a new Declaration have been executed by added inventors Tom Westberg and Rohit Vishnoi and have been submitted with the request. Original inventors Mark R. Vandlik and Michael Kast have also executed the new Declaration. However, original inventor Kelly B. Smith has not, as yet, been located to obtain her signature on the new Declaration. Active efforts are ongoing to locate her and ask her to join in on the execution of the new Declaration.

An assignment, executed by the original inventors Mark Vandlik, Michael Kast, and Kelly B. Smith has been previously recorded in the parent application (Serial Number 09/976833, now US 6,709,412) in Reel/Frame 012582/0905. The assignee Baxter International Inc. has consented to the correction of inventorship.

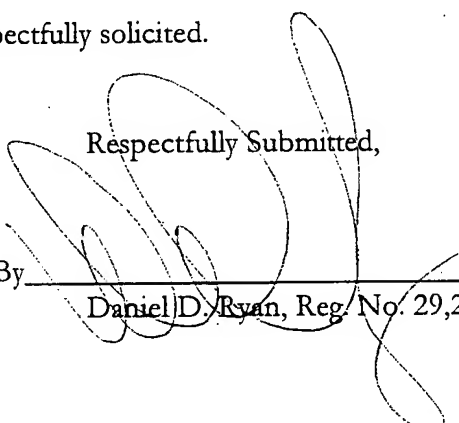
Under such circumstances, as directed by MPEP 201.03 (B), applicant submits this Petition under 37 C.F.R. § 1.183, requesting a waiver of the requirement of 37 C.F.R. § 1.64 that Kelly B. Smith sign the new Declaration, when as here, the assignee has consented to the correction to add new inventors.

The processing fee as set forth in 37 C.F.R. §1.17(i) accompanies this Petition. You are authorized to charge any excess fees, or to credit overpayments, to Deposit Account No. 06-2360. A copy of this Petition is attached for this purpose.

Approval of this Petition is respectfully solicited.

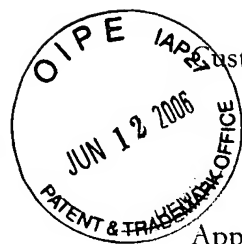
Respectfully Submitted,

By

  
Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308





Customer No.: 26308

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP 2 CON

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: 26 January 2004

Group Art Unit: 3761

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**DECLARATION OF ALLEN L. LEISTEN**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, ALLEN L. LEISTEN, being duly warned do hereby declare:

1. I am an investigator. I was asked by attorney Daniel D. Ryan to attempt to locate the present whereabouts of Kelly B. Smith.

2. On June 6, 2006 I went to the last known address of Kelly B. Smith, 5S486 Arlington Avenue, Naperville, Illinois.

3. When I arrived at the residence, which was a single family home in a residential neighborhood, I rang the door bell and got no response. I gained visual access to the interior of the house through uncovered windows and the house was completely void of furniture. After a period of time a young man appeared from a neighboring residence. I approached him and asked if he knew or had any information on the whereabouts of the people next door at 5S486. He indicated he was not acquainted with them closely but that his mother was.

4. His mother, Mrs. Rickowski resides at 5S508 Arlington Avenue, indicated that the Smiths had sold their house and moved to Stroudsburg, Pennsylvania. She did not have an address; all she knew was the city and state of where they had moved to.

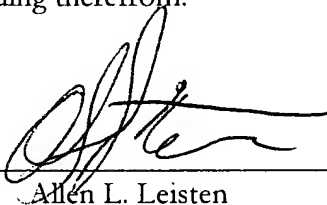
5. I then checked with two local post offices and was informed at each location that they were precluded by law from giving me any address change for the people who resided at 5S486 Arlington Avenue. The post offices indicated that they used to provide that information but a recent law change now prevents them from giving out that information.

6. I went online and found that there are six (6) K. Smiths with listed phone numbers in Stroudsburg, Pennsylvania. Only one had the first name initial "K"; the others had different first names. The number for the "K Smith" in Stroudsburg, Pennsylvania was 570 402 4913. I did not confirm that this was in fact Kelly Smith at this point.

I declare that all statements made herein of my own knowledge are true; all statements made on information and belief are believed to be true; that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC 1001, and that such willful, false statements may jeopardize the validity of the application or of this document or of any patent issuing therefrom.

Dated this 7 day of June, 2006.

By: \_\_\_\_\_



Allen L. Leisten

# RYAN KROMHOLZ & MANION, S.C.

ATTORNEYS AT LAW

Daniel D. Ryan  
Joseph A. Kromholz  
John M. Manion  
Laura A. Dable  
Daniel R. Johnson  
Patrick J. Fleis  
Melissa S. Hockersmith  
Thomas J. Krumenacher

Telephone: (262) 783-1300  
Facsimile: (262) 783-1211  
Toll Free: (800) 686-9333

Est. 1873

Mailing Address:  
P.O. Box 26618  
Milwaukee, WI 53226-0618

Building Address:  
3360 Gateway Road  
Brookfield, WI 53045

Fond du Lac Office:  
74 S. Main Street, Suite 103  
Fond du Lac, WI 54935

Arnold J. Ericson (Of Counsel)  
Donald Cayen (Of Counsel)

2 June 2006

Kelly B. Smith  
5S486 Arlington Avenue  
Naperville, IL 60540

Re: F-5489 CIP 2 CON (USSN 10/765,498)  
Blood Processing Systems and Methods that Employ an In-Line Leukofilter Mounted in a  
Restraining Fixture

Dear Kelly:

We are trying to locate you to have you sign the attached Declaration.

This concerns the filing of a continuation patent application of a case on which you were named a joint inventor along with Mark Vandlik and Michael Kast. The case as originally filed (and which has issued as US Patent No. 6,709,412) was directed to the restraining fixture for the flexible leukodepletion filter. The continuation claims are more broadly directed to the concept of using a pump to direct blood through a flexible filter, and for that reason we added two new inventors, Tom Westberg and Rohit Vishnoi. I attach a copy of the application as filed, and documents signed by Tom, Rohit, Mark and Michael, as well as a consent from the assignee, Baxter to the new list of inventors.

At the time we submitted these papers, we did not know your current whereabouts. We since obtained the above address and a telephone number, but when we called the number we were told it was disconnected. We are sending these materials to the address in the hope that you are still living at this location.

Kindly sign the Declaration at the location tagged and please provide your new address (you can hand-write these in). Please initial and date the new address information.

Please call me or my assistant, Judy Dunaway, as soon as you receive these materials so we can arrange a courier to pick them up and return them to us.

Cordially,  
RYAN KROMHOLZ & MANION, S.C.

By:

Daniel D. Ryan

DDR:jd  
Enclosure - As Stated

**COMBINED DECLARATION AND POWER OF ATTORNEY  
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION OR CIP)**

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type: *(check one applicable item below)*

- ☒ original  
☐ supplemental

Type of Application: *(check one applicable item below)*

- ☐ original  
☐ design

NOTE: *If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.*

- ☐ national stage of PCT

NOTE: *If one of the following items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.*

- ☐ divisional  
☒ continuation  
☐ continuation-in-part (CIP)

**INVENTORSHIP IDENTIFICATION**

WARNING: *If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN  
IN-LINE LEUKOFILTER MOUNTED IN A RESTRAINING FIXTURE

**SPECIFICATION IDENTIFICATION**

the specification of which: *(complete (a), (b) or (c))*

- (a) ☐ is attached hereto.  
(b) ☒ was filed on 26 January 2004 as ☐ Serial No. 10/765,498  
or ☐ Express Mail No., as Serial No. not yet known \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: *Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.*

- (c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
filed on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_  
(if any).

# ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

- [ ] In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

## PRIORITY CLAIM (35 U.S.C. § 119)

- A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

- (d) [ x ] no such applications have been filed.  
(e) [ ] such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]

- B. CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application No.	Filing Date
_____	_____
_____	_____
_____	_____

## CLAIM FOR BENEFIT OF EARLIER US and/or PCT APPLICATION(S) UNDER 35 U.S.C. § 120

- [ ] The claim for the benefit of any such applications are set forth in the attached ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR US PRIORITY CLAIM

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

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NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. S 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Daniel D. Ryan (29,243)  
John M. Manion (38,957)  
Laura A. Dable (46,436)  
Patricia A. Limbach (50,295)  
Thomas J. Krumenacher (56,736)

Bradford R.L. Price (29,101)  
Joseph A. Kromholz (34,204)  
Daniel R. Johnson (46,204)  
Patrick J. Fleis (55,185)  
Melissa S. Hockersmith (56,960)

(check the following item, if applicable)

- [ ] Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

---

SEND CORRESPONDENCE TO

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Deerfield, IL 60015

DIRECT TELEPHONE CALLS TO:  
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Bradford R.L. Price  
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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

MARK (GIVEN NAME) R (MIDDLE INITIAL OR NAME) VANDLIK (FAMILY (OR LAST NAME))  
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Full name of fifth joint inventor, if any

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 Post Office Address 235 WILSON AVENUE  
DEERFIELD, ILLINOIS 60015

**ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR US PRIORITY CLAIM**

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120**

I hereby claim the benefit under Title 35, United States Code, S 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, S 112, I acknowledge the duty to disclose information that is material to the examination of this application, namely, information where there is substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:**

Status  
(CHECK ONE)

U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Abandoned
1. 09/976,833	10/13/2001	X		
2. 09/389,504	09/03/1999			X
3. _____	_____			

**PCT APPLICATIONS DESIGNATING THE U.S.**

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NOS. ASSIGNED (if any)
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

**35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS**

**DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY APPLICATION  
CLAIMED UNDER 35 USC 119**

	Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____



CHECK PROPER BOX(S) FOR ANY OF THE FOLLOWING ADD. PAGE(S) WHICH  
FORM A PART OF THIS DECLARATION

☐ Signature for sixth and subsequent joint inventors.

\*\*\*

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor.

\*\*\*

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47.

\*\*\*

☒ Added page to combined declaration and power of attorney for US Priority Claim

\*\*\*

☐ Authorization of attorney(s) to accept and follow instructions from representative

\*\*\*

*(If no further pages form a part of this declaration then end this declaration with this page and check the following item:)*

☐ This declaration ends with this page

Patent

**BLOOD PROCESSING SYSTEMS AND METHODS  
THAT EMPLOY AN IN-LINE, FLEXIBLE LEUKOFILTER**

**Related Applications**

This application is a continuation of co-  
5 pending United States Application Serial No. 09/976,833,  
filed October 13, 2001, and entitled Blood Separation  
Systems and Methods that Employ an In-Line Leukofilter  
Mounted in a Restraining Fixture," which is a  
continuation-in-part of United States Patent Application  
10 Serial Number 09/389,504, filed September 3, 1999, and  
entitled "Blood Separation Systems and Methods Using a  
Multiple Function Pump Station to Perform Different On-  
Line Processing Tasks," which is incorporated herein by  
reference.

**15 Field of the Invention**

This invention relates to systems and methods  
for processing and collecting blood, blood constituents,  
or other suspensions of cellular material.

**Background of the Invention**

20 Today people routinely separate whole blood,  
usually by centrifugation, into its various therapeutic  
components, such as red blood cells, platelets, and  
plasma.

Conventional blood processing methods use  
25 durable centrifuge equipment in association with single

use, sterile processing systems, typically made of plastic. The operator loads the disposable systems upon the centrifuge before processing and removes them afterwards.

5               Conventional blood centrifuges are of a size that does not permit easy transport between collection sites. Furthermore, loading and unloading operations can sometimes be time consuming and tedious.

10               In addition, a need exists for further improved systems and methods for collecting blood components in a way that lends itself to use in high volume, on line blood collection environments, where higher yields of critically needed cellular blood components, like plasma, red blood cells, and platelets,  
15               can be realized in reasonable short processing times.

              The operational and performance demands upon such fluid processing systems become more complex and sophisticated, even as the demand for smaller and more portable systems intensifies. The need therefore exists  
20               for automated blood processing controllers that can gather and generate more detailed information and control signals to aid the operator in maximizing processing and separation efficiencies.

#### **Summary of the Invention**

25               The invention provides systems and methods for processing blood and blood constituents that lend themselves to portable, flexible processing platforms equipped with straightforward and accurate control functions.

30               One aspect of the invention provides blood processing systems and methods comprising a blood processing set that includes a source of blood cells and a blood component collection flow channel coupled to the source of blood cells. The blood component collection  
35               flow channel includes a blood cell storage container and

an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container. The in-line filter including a fibrous filter medium, first and second flexible housings, and a unitary, continuous peripheral seal. The peripheral seal is characterized by being formed by application of pressure and radio-frequency heating in a single process, to join the first and second flexible housings to each other, as well as join the fibrous filtration medium to the first and second flexible housings. The blood processing system further includes a pump station adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter.

In one embodiment, the blood processing system further includes a fixture to restrain expansion of the first and second filter housings as a result of pressure applied during operation of the pump station.

In one embodiment, the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood. Other features and advantages of the inventions are set forth in the following specification and attached drawings.

#### Brief Description of the Drawings

Fig. 1 is a perspective view of a fluid processing system that embodies features of the invention, with the doors to the centrifuge station and pump and valve station being shown open to accommodate mounting of a fluid processing set;

Fig. 2 is a perspective view of the system shown in Fig. 1, with the doors to the centrifuge station and pump and valve station being shown closed as they would be during fluid processing operations;

Fig. 3 is a schematic view of a representative

blood processing circuit formed by the fluid processing set shown in Figs. 1 and 2;

Fig. 4 is a perspective view of a blood processing chamber and associated fluid conveying umbilicus that form a part of the fluid processing set shown in Figs. 1 and 2;

Fig. 5 is an exploded top perspective view of the of a two-part molded centrifugal blood processing container, which can form a part of the fluid processing set used in association with the device shown in Figs. 1 and 2;

Fig. 6 is a bottom perspective view of the molded processing container shown in Fig. 5;

Fig. 7 is a side section view of the molded processing container shown in Fig. 5, after connection of an umbilicus;

Fig. 8 is a side section view of a three-part molded centrifugal blood processing container which can form a part of the fluid processing set used in association with the device shown in Figs. 1 and 2;

Fig. 9 is a top view of the molded processing container shown in Fig. 5, showing certain details of the separation channel;

Fig. 10 is an exploded perspective view of the centrifuge station and associated centrifuge assembly of the device shown in Figs. 1 and 2;

Fig. 11 is an enlarged exploded perspective view of the centrifuge assembly shown in Fig. 10;

Fig. 12 is a perspective view of the centrifuge assembly fully assembled and housed in the centrifuge station of the device shown in Figs. 1 and 2, with the blood processing chamber and associated umbilicus also mounted on the centrifuge assembly for use;

Fig. 13 is a perspective view of the rotor

plate that forms a part of the centrifuge assembly shown in Figs. 10 to 12, showing the latch assembly which releasably secures the processing chamber to the centrifuge assembly, the latch assembly being shown in  
5 its chamber retaining position;

Fig. 14 is a side section view of the rotor plate shown in Fig. 13, showing the components of the latching assembly as positioned when the latch assembly is in its chamber retaining position;

10 Fig. 15 is a side section view of the rotor plate shown in Fig. 13, showing the components of the latching assembly as positioned when the latch assembly is in its chamber releasing position;

15 Figs. 16 to 18 are a series of perspective view of the centrifuge station of the device shown in Figs. 1 and 2, showing the sequence of loading the processing chamber and associated umbilicus on the centrifuge assembly prior to use;

20 Figs. 19 to 22 are a series of perspective view of the centrifuge station of the device shown in Figs. 1 and 2, after loading the processing chamber and associated umbilicus on the centrifuge assembly, showing at ninety degree intervals the travel of the umbilicus to impart rotation to the processing chamber, as driven and  
25 restrained by umbilicus support members carried by the yoke;

Fig. 23 is a schematic view of a fluid processing circuit of the type shown in Fig. 3, showing certain details of the arrangement of pumps that convey  
30 blood and fluid through the circuit;

Figs. 24A and 24B are perspective views of a leukofilter that can form a part of the fluid process circuit shown in Figs. 3 and 23, the leukofilter comprising a filter media enclosed between two flexible  
35 sheets of plastic material, Fig. 24A showing the

leukofilter in an exploded view and Fig. 24B showing the leukofilter in an assembled view;

5 Figs. 25A and 25B are perspective views of the leukofilter shown in Fig. 24B in association with a fixture that retains the leukofilter during use, Fig. 25A showing the leukofilter being inserted into an opened fixture and Fig. 25B showing the leukofilter retained for use within a closed fixture;

10 Fig. 26 is a perspective view of a device of a type of shown in Figs. 1 and 2, with the lid of the device closed to also reveal the location of various components and a leukofilter holder carried on the exterior of the lid;

15 Fig. 27 is a partial perspective view of a side of the base of a device of a type shown in Figs. 1 and 2, showing a holder for supporting the leukofilter retaining fixture shown in Figs. 25A and 25B during fluid processing operations;

20 Fig. 28 is a view of one side of the leukofilter retaining fixture of a type shown in Figs. 25A and 25B, showing a mounting bracket that can be used to secure the leukofilter either to the lid-mounted receptacle shown in Fig. 26 or the base-mounted holder shown in Fig. 27; and

25 Fig. 29 is an exploded perspective view of a cassette, which can form a part of the processing set used in association with the processing device shown in Figs. 1 and 2, and the pump and valve station on the processing device, which receives the cassette for use.

30 The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall  
35 within the meaning and range of equivalency of the claims

are therefore intended to be embraced by the claims.

#### Description of the Preferred Embodiments

Fig. 1 shows a fluid processing system 10 that embodies the features of the invention. The system 10  
5 can be used for processing various fluids.

The system 10 is particularly well suited for processing whole blood and other suspensions of biological cellular materials. Accordingly, the illustrated embodiment shows the system 10 used for this  
10 purpose.

#### I. System Overview

The system 10 includes three principal components. These are: (i) a liquid and blood flow set 12 (shown schematically in Fig. 3); (ii) a blood processing device  
15 14 (see Figs. 1 and 2), which interacts with the flow set 12 to cause separation and collection of one or more blood components; and (iii) a controller 16 carried on board the device 14, which governs the interaction to perform a blood processing and collection procedure  
20 selected by the operator.

#### A. The Processing Device and Controller

The blood processing device 14 and controller 16 are intended to be durable items capable of long term use. In the illustrated and preferred embodiment, the blood  
25 processing device 14 and controller 16 are mounted inside a portable housing or case 36. The case 36 presents a compact footprint, suited for set up and operation upon a table top or other relatively small surface. The case 36 is also intended to be transported easily to a collection  
30 site.

The case 36 includes a base 38 and a hinged lid 40, which opens for use (as Fig. 1 shows). In use, the base 38 is intended to rest in a generally horizontal support surface. The lid 40 also closes for transport (see Fig.  
35 26).



The case 36 can be formed into a desired configuration, e.g., by molding. The case 36 is preferably made from a lightweight, yet durable, plastic material.

5       The controller 16 carries out process control and monitoring functions for the system 10. The controller 16 comprises a main processing unit (MPU), which can comprise, e.g., a Pentium™ type microprocessor made by Intel Corporation, although other types of conventional  
10 microprocessors can be used. The MPU can be mounted inside the lid 40 of the case 36.

Preferably, the controller 16 also includes an interactive user interface 260, which allows the operator to view and comprehend information regarding the  
15 operation of the system 10. In the illustrated embodiment, the interface 260 includes an interface screen carried in the lid 40, which displays information for viewing by the operator in alpha-numeric format and as graphical images.

20       Further details of the controller 16 can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference. Further details of the interface can be found in Lyle et al, United States Patent 5,581,687, which is also incorporated herein by  
25 reference.

As Fig. 26 shows, the lid 40 can be used to support other input/outputs to couple other external devices to the controller 16 or other components of the device 14. For example, an ethernet port 50, or an input 52 for a  
30 bar code reader or the like (for scanning information into the controller 16), or a diagnostic port 54, or a port 56 to be coupled to a pressure cuff 58 (see Fig. 3), or a system transducer calibration port 60, can all be conveniently mounted for access on exterior of the lid  
35 40, or elsewhere on the case 36 of the device 14.

### B. The Flow Set

The flow set 12 (see Fig. 3), is intended to be a sterile, single use, disposable item. Before beginning a given blood processing and collection procedure, the operator loads various components of the flow set 12 in the case 36 in association with the device 14 (as Figs. 1 and 2 show). The controller 16 implements the procedure based upon preset protocols, taking into account other input from the operator. Upon completing the procedure, the operator removes the flow set 12 from association with the device 14. The portion of the set 12 holding the collected blood component or components are removed from the case 36 and retained for storage, transfusion, or further processing. The remainder of the set 12 is removed from the case 36 and discarded.

The flow set 12 can take various forms. In the illustrated embodiment (see Figs. 1 and 3), the flow set includes a blood processing chamber 18 designed for use in association with a centrifuge. Accordingly, the processing device 14 includes a centrifuge station 20 (see Fig. 1), which receives the processing chamber 18 for use (see Fig. 12).

As Fig. 1 shows, the centrifuge station 20 comprises a compartment 21 formed in the base 38. The centrifuge station 20 includes a door 22, which opens and closes the compartment 21. The door 22 opens (as Fig. 1 shows) to allow loading of the processing chamber 18 into the compartment 21. The door 22 closes (as Fig. 2 shows) to enclose the processing chamber 18 within the compartment 21 during operation.

The centrifuge station 20 rotates the processing chamber 18. When rotated, the processing chamber 18 centrifugally separates whole blood received from a donor into component parts, e.g., red blood cells, plasma, and platelets.

In the illustrated embodiment, the set 12 also includes a fluid pressure actuated cassette 28 (see Fig. 29). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. In the illustrated embodiment, the fluid pressure comprises positive and negative pneumatic pressure. Other types of fluid pressure can be used.

The cassette 28 can take various forms. In a preferred embodiment (see Fig. 29), the cassette 28 comprises an injection molded body 200 made of a rigid medical grade plastic material. Flexible diaphragms 202, preferably made of flexible sheets of medical grade plastic, overlay the front side and back sides of the cassette 28. The diaphragms are sealed about their peripheries to the peripheral edges of the front and back sides of the cassette 28.

As Fig. 29 shows, the cassette 28 has an array of interior cavities formed on both the front and back sides. The interior cavities define pneumatic pump stations (schematically designated PS in Fig. 3), which are interconnected by a pattern of fluid flow paths (schematically designated FP in Fig. 3) through an array of in line, pneumatic valves (schematically designated V in Fig. 3).

As Figs. 1 and 29 show, the cassette 28 interacts with a pneumatic actuated pump and valve station 30, which is mounted in the lid of the 40 of the case 36. The pump and valve station 30 includes a cassette holder 216. A door 32 is hinged to move with respect to the cassette holder 216 between an opened position, exposing the cassette holder 216 (shown in Fig. 1) for loading and unloading the cassette 28, and a closed position, enclosing the cassette 28 within the pump and valve station 30 for use (shown in Fig. 2). The pump and valve

station 30 includes pneumatic actuator ports 204 (see Fig. 29) that apply positive and negative pneumatic pressure upon the diaphragms of the cassette 28. The pneumatic pressures displace the diaphragms 202 with respect to the pump chambers and valves, to thereby direct liquid flow through the cassette 28.

Further details of the cassette 28 and the operation of the pump and valve station 30 can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

Referred back to Fig. 3, the flow set 16 also includes an array of tubes and containers in flow communication with the cassette 28. The arrangement of tubes and containers can vary according to the processing objectives. The system 10 can be operated to collect red blood cells, plasma, red blood cells and plasma, and platelets.

In the illustrated embodiment, the flow set 16 is arranged to support the centrifugal collection of two units of red blood cells (about 360 ml), and to filter the red blood cells to reduce the number of leukocytes prior to storage. During this procedure, whole blood from a donor is centrifugally processed in the chamber 18 into red blood cells (in which a majority of the leukocytes resides) and a plasma constituent (in which a majority of the platelets resides). The plasma constituent is returned to the donor, while the targeted volume of red blood cells is collected, filtered to reduce the population of leukocytes, and placed into containers for storage mixed with a red blood cell storage solution.

In this configuration (see Fig. 3), the flow set 16 includes a donor tube 266 having an attached phlebotomy needle 268. The donor tube 266 is coupled to a port of the cassette 28.

As Fig. 3 shows, a pressure cuff 58 is desirable used to enhance venous blood flow through the phlebotomy needle 268 during blood processing. The pressure cuff 58 is coupled to the pressure cuff port 56 on the lid 40 (as previously described), and the pressure supplied to the cuff 58 is desirably controlled by the controller 16. The controller 16 can also operate a vein pressure display 62 (see Fig. 26), which shows vein pressure at the pressure cuff 56.

10 An anticoagulant tube 270 is coupled to the phlebotomy needle 268. The anticoagulant tube 270 is coupled to another cassette port. A container 276 holding anticoagulant is coupled via a tube 274 to another cassette port.

15 A container 288 holding saline is coupled via a tube 284 to another cassette port.

The set 16 further includes tubes 290, 292, 294, which extend to an umbilicus 296. When installed in the processing station, the umbilicus 296 links the rotating processing chamber 18 with the cassette 28 without need for rotating seals. In a preferred embodiment, the umbilicus 296 is made from rotational-stress-resistant Hytrel® copolyester elastomers (DuPont). Further details of the construction of the umbilicus 296 will be provided later.

25 The tubes 290, 292, and 294 are coupled, respectively, to other cassette ports. The tube 290 conveys whole blood into the processing chamber 18. The tube 292 conveys plasma constituent from the processing chamber 18. The tube 294 conveys red blood cells from processing chamber 18.

A plasma collection reservoir 304 is coupled by a tube 302 to a cassette port. The collection reservoir 304 is intended, in use, to serve as a reservoir for the plasma constituent during processing prior to its return

35

to the donor.

A red blood cell collection reservoir 308 is coupled by a tube 306 to a cassette port. The collection reservoir 308 is intended, in use, to receive red blood  
5 cells during processing. for storage.

Two red blood cell storage containers 307 and 309 are coupled by a tube 311 to another cassette port. A leukocyte reduction filter 313 is carried in line by the tube 311. During processing, red blood cells are  
10 transferred from the red blood cell collection reservoir 308 through the filter 313 into the storage containers 307 and 309.

A container 208 holding a red blood cell storage or additive solution is coupled via a tube 278 to another  
15 cassette port. The red blood cell storage solution is metered into the red blood cells as they are conveyed from the container 308, through the filter 313, into the storage containers 307 and 309. Further details of this aspect of the collection process will be described later.

20 A whole blood reservoir 312 is coupled by a tube 310 to a cassette port. The collection container 312 is intended, in use, to serve as a reservoir for whole blood during processing.

In the illustrated embodiment, the set 16 further  
25 includes a fixture 338 (see Fig. 4) to hold the tubes 292 and 294 in viewing alignment with an optical sensing station 332 in the base 36 (see Fig. 12). The sensing station 332 optically monitors the presence or absence of targeted blood components (e.g., platelets and red blood  
30 cells) conveyed by the tubes 292 and 294. The sensing station 332 provides output reflecting the presence or absence of such blood components. This output is conveyed to the controller 16. The controller 16 processes the output and generates signals to control processing events  
35 based, in part, upon the optically sensed events. Further

details of the operation of the controller to control processing events based upon optical sensing can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

5       As Fig. 12 shows, the sensing station 332 is desirably located within the confines of the centrifuge station 20. This arrangement minimizes the fluid volume of components leaving the chamber before monitoring by the sensing station 332.

10       The fixture 338 gathers the tubes 292 and 294 in a compact, organized, side-by-side array, to be placed and removed as a group in association with the sensing station 332. In the illustrated embodiment, the fixture 338 also holds the tube 290, which conveys whole blood  
15       into the processing chamber 18, even though no associated sensor is provided. The fixture 338 serves to gather and hold all tubes 290, 292, and 294 that are coupled to the umbilicus 296 in a compact and easily handled bundle.

      The fixture 338 can be an integral part of the  
20       umbilicus 296, formed, e.g., by over molding. Alternatively, the fixture 338 can be a separately fabricated part, which snap fits about the tubes 290, 292, and 294 for use.

      As Figs. 1 and 2 also show, the case 36 contains  
25       other components compactly arranged to aid blood processing. In addition to the centrifuge station 20 and pump and valve station 30, already described, the case 36 includes a weigh station 238 and one or more trays 212 or hangers 248 for containers. The arrangement of these  
30       components in the case 36 can vary.

      In the illustrated embodiment, the weigh station 238 comprises a series of container hangers/weigh sensors 246 arranged along the top of the lid 40. In use, the containers 304, 308, 312 are suspended on the  
35       hangers/weigh sensors 246.

The holding trays 212 comprise molded recesses in the base 38. The trays 212 accommodate the containers 276 (containing anticoagulant) and 208 (containing the red blood cell additive solution). In the illustrated embodiment, an additional swing-out side hanger 248 is also provided on the side of the lid 40. The hanger 248 (see Fig. 2) supports the container 288 (containing saline) during processing. Other swing out hangers 249 support the red blood cells storage containers 307 and 309.

In the illustrated embodiment, the tray 212 holding the container 276 and the hanger 248 also include weigh sensors 246.

As blood or liquids are received into and/or dispensed from the containers during processing, the weigh sensors 246 provide output reflecting weight changes over time. This output is conveyed to the controller 16. The controller 16 processes the incremental weight changes to derive fluid processing volumes. The controller generates signals to control processing events based, in part, upon the derived processing volumes. Further details of the operation of the controller to control processing events can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

### C. The Centrifugal Processing Chamber

Figs. 5 to 7 show an embodiment of the centrifugal processing chamber 18, which can be used in association with the system 10 shown in Fig. 1 to perform the intended red blood cell collection procedure. In the illustrated embodiment, the processing chamber 18 is preformed in a desired shape and configuration, e.g., by injection molding, from a rigid, biocompatible plastic material, such as a non-plasticized medical grade acrylonitrile-butadiene-styrene (ABS).



In one arrangement, the chamber 18 can be fabricated in two separately molded pieces; namely (as Figs. 5 to 7 show), a base 388 and a lid 150. The base 388 includes a center hub 120. The hub 120 is surrounded radially by inside and outside annular walls 122 and 124. Between them, the inside and outside annular walls 122 and 124 define a circumferential blood separation channel 126. A molded annular wall 148 closes the bottom of the channel 126.

The top of the channel 126 is closed by the separately molded, flat lid 150 (which is shown separated in Fig. 5 for the purpose of illustration). During assembly (see Fig. 7), the lid 150 is secured to the top of the chamber 18, e.g., by use of a cylindrical sonic welding horn.

All contours, ports, channels, and walls that affect the blood separation process may be preformed in the base 388 in a single, injection molded operation, during which molding mandrels are inserted and removed through the open end of the base 388 (shown in Fig. 5). The lid 150 comprises a simple flat part that can be easily welded to the open end of the base 388 to close it after molding. Because all features that affect the separation process are incorporated into one injection molded component, any tolerance differences between the base 388 and the lid 150 will not affect the separation efficiencies of the chamber 18.

The contours, ports, channels, and walls that are preformed in the base 388 may create surfaces within the base 388 that do not readily permit the insertion and removal of molding mandrels through a single end of the base 388. In this arrangement, the base 388 can be formed by separate molded parts, either by nesting cup shaped subassemblies or two symmetric halves.

Alternatively, molding mandrels can be inserted and

removed from both ends of the base 388. In this arrangement (see Fig. 8), the chamber 18 can be molded in three pieces; namely, the base 388, the lid 150 (which closes one end of the base 388 through which top molding  
5 mandrels are inserted and removed), and a separately molded insert 151 (which closes the other end of the base 388 through which bottom molding mandrels are inserted and removed).

The contours, ports, channels, and walls that are  
10 preformed in the base 388 can vary.

As seen in Fig. 9, in one arrangement, the inside annular wall 122 is open between one pair of stiffening walls. The opposing stiffening walls form an open interior region 134 in the hub 120, which communicates  
15 with the channel 126. Blood and fluids are introduced from the umbilicus 296 into and out of the separation channel 126 through this region 134.

In this embodiment (as Fig. 9 shows), a molded interior wall 136 formed inside the region 134 extends  
20 entirely across the channel 126, joining the outside annular wall 124. The wall 136 forms a terminus in the separation channel 126, which interrupts flow circumferentially along the channel 126 during separation.

Additional molded interior walls divide the region  
25 134 into three passages 142, 144, and 146. The passages 142, 144, and 146 extend from the hub 120 and communicate with the channel 126 on opposite sides of the terminus wall 136. Blood and other fluids are directed from the  
30 hub 120 into and out of the channel 126 through these passages 142, 144, and 146.

The underside of the base 388 (see Fig. 7) includes a shaped receptacle 179. The far end of the umbilicus 296 includes a shaped mount 178 (see Figs. 24 and 24A). The  
35 mount 178 is shaped to correspond to the shape of the

receptacle 179. The mount 178 can thus be plugged into the receptacle 179 (as Fig. 7 shows), to couple the umbilicus 296 in fluid communication with the channel 126.

5       The mount 178 is desirably made from a material that can withstand considerable flexing and twisting, to which the mount 178 can be subjected during use, e.g., Hytrel® 3078 copolyester elastomer (DuPont). The dimensions of the shaped receptacle 179 and the shaped mount 178 are  
10       preferably selected to provide a tight, dry press fit, to thereby avoid the need for solvent bonding or ultrasonic welding techniques between the mount 178 and the base 388 (which can therefore be formed from an incompatible material, such as ABS plastic).

15       D.     The Centrifuge Assembly

      The centrifuge station 20 (see Fig. 10) includes a centrifuge assembly 48. The centrifuge assembly 48 is constructed to receive and support the molded processing chamber 18 and umbilicus 296 for use.

20       As illustrated (see Figs. 10 and 11), the centrifuge assembly 48 includes a yoke 154 having bottom, top, and side walls 156, 158, 160. The yoke 154 spins on a bearing element 162 (Fig. 11) attached to the bottom wall 156. An electric drive motor 164 is coupled to the bottom  
25       wall 156 of the yoke 154, to rotate the yoke 154 about an axis 64. In the illustrated embodiment, the axis 64 is essentially horizontal (see Fig. 1), although other angular orientations can be used.

      A rotor plate 166 (see Fig. 11) spins within the  
30       yoke 154 about its own bearing element 168, which is attached to the top wall 158 of the yoke 154. The rotor plate 166 spins about an axis that is generally aligned with the axis of rotation 64 of the yoke 154.

      As Fig. 7 best shows, the top of the processing  
35       chamber 18 includes an annular lip 380, to which the lid

150 is secured. As Fig. 12 shows, the rotor plate 166 includes a latching assembly 382 that removably grips the lip 380, to secure the processing chamber 18 on the rotor plate 166 for rotation.

5       The configuration of the latching assembly 382 can vary. In the illustrated embodiment (see Figs. 13 to 15), the latching assembly 382 includes a latch arm 66 pivotally mounted on a pin in a peripheral recess 68 in the rotor plate 166. The latch arm 66 pivots between a  
10   retaining position (shown in Figs. 13 and 14) and a releasing position (shown in Fig. 15).

      In the retaining position (see Fig. 14), an annular groove 70 on the underside of the latch arm 66 engages the annular lip 380 of the processing chamber 18. The  
15   annular groove 70 on the latch arm 66 coincides with an annular groove 71 that encircles the top interior surface of the rotor plate 166. The engagement of the lip 380 within the groove 70/71 secures the processing chamber 18 to the rotor plate 166.

20       In the releasing position (see Fig. 15), the annular groove 70 is swung free of engagement of the annular lip 380. This lack of engagement allows release of the processing chamber 18 from the remainder of the groove 71 in the rotor plate 166.

25       In the illustrated embodiment, the latching assembly 382 includes a sliding pawl 72 carried in a radial track 74 on the top of the rotor plate. In the track 74, the pawl 72 slides radially toward and away from the latch arm 66.

30       When the latch arm 66 is in its retaining position and the pawl 72 is located in a radial position adjacent the latch arm 66 (see Fig. 14), a finger 76 on the pawl 72 slips into and engages a cam recess 78 in the latch arm 66. The engagement between the pawl finger 76 and  
35   latch arm cam recess 78 physically resists movement of

the latch arm 66 toward the releasing position, thereby locking the latch arm 66 in the retaining position.

5 A spring 80 within the pawl 72 normally biases the pawl 72 toward this radial position adjacent the latch arm 66, where engagement between the pawl finger 76 and latch arm cam recess 78 can occur. The latch arm 66 is thereby normally held by the pawl 72 in a locked, retaining position, to hold the processing chamber 18 during use.

10 The pawl 72 can be manually moved against the bias of the spring 80 radially away from its position adjacent the latch arm 66 (see Fig. 15). During this movement, the finger 76 on the pawl 72 slips free of the cam recess 78 in the latch arm 66. Free of engagement between the pawl  
15 finger 76 and latch arm cam recess 78, the latch arm 66 is unlocked and can be pivoted toward its releasing position. In the absence of manual force against the bias of the spring 80, the pawl 72 returns by spring force toward its position adjacent the latch arm 66, to  
20 lock the latch arm 66 in the chamber retaining position.

In the illustrated embodiment (see Fig. 13), the top wall 158 of the yoke 154 carries a downward depending collar 82. The collar 82 rotates in unison with the yoke 154, relative to the rotor plate 166. The collar 82  
25 includes a sidewall 84 that is continuous, except for a cut away or open region 86.

As Fig. 17 best shows, the pawl 72 includes an upstanding key element 88. The sidewall 84 of the collar 82 is located in the radial path that the key element 88  
30 travels when the pawl 72 is manually moved against the bias of the spring 80 radially away from its position adjacent the latch arm 66. The key element 88 abuts against the collar sidewall 84, to inhibit movement of the pawl 72 in this direction, unless the open region 86  
35 is aligned with the key element 88, as shown in Figs. 13

and 15. The open region 86 accommodates passage of the key element 88, permitting manual movement of the pawl 72 against the bias of the spring 80 radially away from its position adjacent the latch arm 66, thereby allowing the  
5 latch arm 66 to pivot into its releasing position.

The interference between the collar sidewall 84 and the key element 88 of the pawl 72 prevents manual movement of the pawl 72 away from the latch arm 66, to  
10 unlock the latch arm 66 for movement into its releasing position, unless the open region 86 and the key element 88 register. The open region 86 is aligned on the yoke 154 so that this registration between the open region 86 and the key element 88 occurs only when the rotor plate 166 is in a prescribed rotational position relative to  
15 the yoke 154. In this position (see Fig. 12), the sidewalls 160 of the yoke 154 are located generally parallel to the plane of the opening to the compartment, providing open access to the interior of the yoke 154. In this position (see Fig. 16), the processing chamber 18  
20 can be freely placed without interference into the interior of the yoke 154, and loaded onto the rotor plate 166. In this position, uninhibited manual movement of the pawl 72 allows the operator to pivot the latch arm 66 into its releasing position, to bring the lid 150 of the  
25 chamber 18 into contact against the rotor plate 166. Subsequent release of the pawl 72 returns the pawl 72 toward the latch arm 66 and allows the operator to lock the latch arm 66 in its retaining position about the lip 380 of the chamber 18. The reverse sequence is  
30 accommodated when it is time to remove the processing chamber 18 from the rotor plate 166.

This arrangement makes possible a straightforward sequence of acts to load the processing chamber 18 for use and to unload the processing chamber 18 after use  
35 (see Fig. 16). As Figs. 17 and 18 further show, easy

loading of the umbilicus 296 is also made possible in tandem with fitting the processing chamber 18 to the rotor plate 166.

5 A sheath 182 on the near end of the umbilicus 296 fits into a preformed, recessed pocket 184 in the centrifuge station 20. The pocket 184 holds the near end of the umbilicus 296 in a non-rotating stationary position aligned with the mutually aligned rotational axes 64 of the yoke 154 and rotor plate 166.

10 The preformed pocket 184 is also shaped to accommodate loading of the fixture 338 at the same time the sheath 182 is inserted. The tubes 290, 292, and 294 are thereby placed and removed as a group in association with the sensing station 332, which is located within the  
15 pocket 184.

Umbilicus support members 186 and 187 (see Fig. 12) are carried by a side wall 160 of the yoke 154. When the rotor plate 166 is located in its prescribed rotational position to enable easy loading of the chamber 18 (see  
20 Figs. 17 and 18), the support members 186 and 187 are presented on the left side of the processing chamber 18 to receive the umbilicus 296 at the same time that the sheath 182 and fixture 338 are manipulated for fitting into the pocket 184.

25 As Fig. 19 shows, one member 186 receives the mid portion of the umbilicus 296. The member 186 includes a surface 188 against which the mid portion of the umbilicus 296 rests. The surface 188 forms a channel that extends generally parallel to the rotational axis 64 and  
30 that accommodates passage of the mid portion of the umbilicus 296. The surface 188 inhibits travel of the mid portion of the umbilicus 296 in radial directions toward and away from the rotational axis 64. However, the surface 188 permits rotation or twisting of the  
35 umbilicus 296 about its own axis.

The other member 187 receives the upper portion of the umbilicus 296. The member 187 includes a surface 190 against which the upper portion of the umbilicus 296 rests. The surface 190 forms a channel inclined toward the top wall 158 of the yoke 154. The surface 190 guides the upper portion of the umbilicus 296 toward the recessed pocket 184, which is located axially above the top wall 158 of the yoke 154, where the umbilicus sheath 182 and fixture 338 are fitted. Like the surface 188, the surface 190 inhibits travel of the upper portion of the umbilicus 296 in radial directions toward and away from the rotational axis 64. However, like the surface 188, the surface 190 permits rotation or twisting of the umbilicus 296 about its own axis.

Closing the centrifuge station door 20 positions a holding bracket 90 on the underside of the door 20 in registry with the sheath 182 (see Figs. 17 and 18). Another holding bracket 92 on the underside of the door 20 is positioned in registry with the fixture 338 when the door 20 is closed. A releasable latch 94 preferably holds the door shut during operation of the centrifuge assembly 48.

During operation of the centrifuge assembly 48 (see Figs. 19 to 22), the support members 186 and 187 carry the umbilicus 296 so that rotation of the yoke 154 also rotates the umbilicus 296 in tandem about the yoke axis. Constrained within the pocket 184 at its near end (i.e., at the sheath 182) and coupled to the chamber 16 at its far end (i.e., by the mount 178), the umbilicus 296 twists upon the surfaces 188 and 190 about its own axis as it rotates about the yoke axis 64, even as the surfaces 188 and 190 inhibit radial travel of the umbilicus relative to the rotation axis 64. The twirling of the umbilicus 296 about its axis as it rotates upon the surfaces 188 and 190 at one omega with the yoke 154



(typically at a speed of about 2250 RPM) imparts a two omega rotation to the processing chamber 18 secured for rotation on the rotor plate 166.

5 The relative rotation of the yoke 154 at a one omega rotational speed and the rotor plate 166 at a two omega rotational speed, keeps the umbilicus 296 untwisted, avoiding the need for rotating seals. The illustrated arrangement also allows a single drive motor 164 to impart rotation, through the umbilicus 296, to the  
10 mutually rotating yoke 154 and processing chamber 18 carried on the rotor plate 166. Further details of this arrangement are disclosed in Brown et al U.S. Patent 4,120,449, which is incorporated herein by reference.

15 The umbilicus 296 can stretch in response to the rotational forces it encounters. The dimensions of a given umbilicus 296 are also subject to normal manufacturing tolerances. These factors affect the flight radius of the umbilicus 296 during use; as well as the stress encountered by the mount 178 at the far end of the  
20 umbilicus 296, which serves as the two omega torque transmitter to drive the processing chamber 18; as well as the lateral loads acting on the centrifuge and motor bearings.

As Figs. 19 to 22 show, the support members 186 and  
25 187 on the yoke serve to physically confine the flight of the umbilicus 296 between the one omega region (mid portion) and two omega region (far end portion), as well as between the one omega region (mid portion) and zero omega region (near end portion) of the umbilicus 296. By  
30 confining the umbilicus 296 to a predefined radial distance from and radial orientation with respect to the rotational axis of the centrifuge assembly 48, the support members 186 and 187 serve to attenuate the factors that can affect umbilicus performance and  
35 endurance.

The support members 186 and 187 make possible a bearing-less umbilicus assembly with no moving parts, while leading to reduced stress at the two omega torque region, where stresses tend to be greatest. The surfaces 188 and 190 of the support members 186 and 187 can be formed and oriented to accommodate rotation of the umbilicus 296 and the driving of the processing chamber 18 in either clockwise or counterclockwise directions.

In the illustrated embodiment, the surfaces 188 and 190 of the support members 186 and 187 are preferably fabricated from a low friction material, to thereby eliminate the need for external lubrication or rotating bearings on the umbilicus 296 itself. The material used can, e.g., comprise Teflon® polytetrafluoroethylene material (DuPont) or an ultra high molecular weight polyethylene. Made from such materials, the surfaces 188 and 190 minimize umbilicus drive friction and the presence of particulate matter due to umbilicus wear.

In a representative embodiment (see Fig. 4), the umbilicus 296 desirably comprises a two layer co-extruded assembly. The interior or core layer 96 desirably comprises Hytrel® 4056 copolyester elastomer (DuPont). The outside layer 98 desirably comprises Hytrel® 3078 copolyester elastomer (DuPont). The outside layer 98 may comprise a relatively thin extrusion, compared to the core layer 96.

In this arrangement, the outside layer 98 of Hytrel® 3078 copolyester elastomer serves as a compatible interface to accommodate over-molding of the zero omega sheath 182 and the two omega mount 178, which may comprise the same Hytrel® 3078 material or an otherwise compatible material. Absent material compatibility, solvents (e.g., methylene chloride) or other forms of surface treatment may be required to facilitate a robust bond between these elements and the umbilicus. Hytrel®

3078 material is desired for the sheath 182, and the mount 178 because it can withstand considerable flexing and twisting forces, to which these regions of the umbilicus are subjected during use.

- 5       The core layer 96 of Hytrel® 4056 copolyester elastomer can be readily solvent bonded to conventional flexible medical grade polyvinyl tubing, from which the tubes 290, 292, and 294 are desirably made.

## II. Double Red Blood Cell Collection Procedure

- 10       Use of the set 12 in association with the device 14 and controller 16 to conduct a typical double unit red blood cell collection procedure will now be described for illustrative purposes.

### A. The Cassette

- 15       The cassette 28 used for a procedure of this type desirably includes dual pneumatic pump chambers PP3 and PP4 (see Fig. 23) which are operated by the controller 16 in tandem to serve as a general purpose, donor interface pump. The dual donor interface pump chambers PP3 and PP4  
20       work in parallel. One pump chamber draws fluid, while the other pump chamber expels fluid. The dual pump chambers PP3 and PP4 thereby alternate draw and expel functions to provide a uniform outlet flow.

- The cassette 28 also desirably includes a pneumatic  
25       pump chamber PP5, which serves as a dedicated anticoagulant pump, to draw anticoagulant from the container 276 and meter the anticoagulant into the blood drawn from the donor.

- The cassette 28 also desirably includes a pneumatic  
30       pump chamber PP1 that serves as a dedicated in-process whole blood pump, to convey whole blood from the reservoir 312 into the processing chamber 18. The dedicated function of the pump chamber PP1 frees the donor interface pump chambers PP3 and PP4 from the added  
35       function of supplying whole blood to the processing

chamber 18. Thus, the in-process whole blood pump chamber PP1 can maintain a continuous supply of blood to the processing chamber 18, while the donor interface pump chambers PP3 and PP4 operate in tandem to simultaneously  
5 draw and return blood to the donor through the single phlebotomy needle. Processing time is thereby minimized.

The cassette 28 also desirably includes a pneumatic pump chamber PP2 that serves as a plasma pump, to convey plasma from the processing chamber 18. The ability to  
10 dedicate separate pumping functions provides a continuous flow of blood into and out of the processing chamber 18, as well as to and from the donor.

#### B. Capacitive Flow Sensing

The controller 16 desirably includes means for  
15 monitoring fluid flow through the pump chambers PP1 to PP5. In the illustrated embodiment, the pump and valve station 30 carries electrode circuits 206 associated with each pump chamber PP1 to PP5. The electrode circuits 206 can be located, e.g., within the pneumatic actuator ports  
20 204 in the pump and valve station 30 (see Fig. 29) that apply negative and positive pressure to the diaphragms to thereby draw fluid into the chambers PP1 to PP5 and expel fluid from the chambers PP1 to PP5. The electrode circuits 206 are coupled to an electrical source and are  
25 in electrical conductive contact with fluids within their respective pump chambers PP1 and PP5.

The passage of electrical energy through each electrode circuit 206 creates an electrical field within the respective pump chamber PP1 to PP5. Cyclic deflection  
30 of the diaphragm associated with a given pump chamber to draw fluid into and expel fluid from the pump chamber PP1 to PP5 changes the electrical field, resulting in a change in total capacitance of the circuit through the electrode. Capacitance increases as fluid is draw into  
35 the pump chamber PP1 to PP5, and capacitance decreases as

fluid is expelled from pump chamber PP1 to PP5.

In the arrangement, the electrode circuits 206 each includes a capacitive sensor (e.g., a Qprox E2S). The capacitive sensor registers changes in capacitance for the electrode circuit 206 for each pump chamber PP1 to PP5. The capacitance signal for a given electrode circuit 206 has a high signal magnitude when the pump chamber is filled with liquid, has a low signal magnitude signal when the pump chamber is empty of fluid, and has a range of intermediate signal magnitudes when the diaphragm occupies intermediate positions.

At the outset of a blood processing procedure, the controller 16 can calibrate the difference between the high and low signal magnitudes for each sensor to the maximum stroke volume of the respective pump chamber. The controller 16 can then relate the difference between sensed maximum and minimum signal values during subsequent draw and expel cycles to fluid volume drawn and expelled through the pump chamber. The controller 16 can sum the fluid volumes pumped over a sample time period to yield an actual flow rate.

The controller 16 can compare the actual flow rate to a desired flow rate. If a deviance exists, the controller 16 can vary pneumatic pressure pulses delivered to the actuators for the pump chambers PP1 to PP5 to minimize the deviance.

The controller 16 can also operate to detect abnormal operating conditions based upon the variations in the electric field and to generate corresponding alarm outputs. The controller 16 can, e.g., monitor for an increase in the magnitude of the low signal magnitude over time. The increase in magnitude reflects the presence of air inside a pump chamber.

For example, the controller 16 can generate a derivative of the signal output of the sensor 426.

Changes in the derivative, or the absence of a derivative, reflects a partial or complete occlusion of flow through the pump chamber PP1 to PP5. The derivative itself also varies in a distinct fashion depending upon whether the occlusion occurs at the inlet or outlet of the pump chamber PP1 to PP5.

#### 1. Monitoring Vein Flow Conditions

By using capacitive sensing and by also counting pump strokes (i.e., the application of negative pressure upon the diaphragm of a given pump chamber to draw fluid into the chamber), the controller 16 can also monitor vein flow conditions, and, in particular, assess and respond to real or potential vein occlusion conditions.

When blood is pumped from the donor, the donor's vein may show difficulties in keeping up with the commanded draw rate that operation of the donor pump chambers PP3/PP4 imposes. In the case of restricted blood flow from the donor, the donor pumps PP3 and PP4 do not fill properly in response to the commanded sequence of pump strokes. The controller 16 attempts to assess and mediate blood supply interruptions due to vein problems before generating a vein occlusion alarm, which suspends processing.

For example, the controller 16 can count the number of consecutive attempted pump strokes for which no blood flow into the pump chambers PP3 and PP4 occurs (which blood flow or absence of blood flow can be detected by capacitive sensing, as above described). A potential donor draw occlusion condition can be deemed to occur when a prescribed number (e.g., 3) of consecutive incomplete fill donor pump strokes takes place.

When a potential donor draw occlusion condition is detected, the controller 16 attempts to rectify the condition by increasing pressure of the pressure cuff 58 and/or decreasing the commanded draw rate, before

generating a processing-halting vein occlusion alarm.

More particularly, in a representative implementation, when a donor draw occlusion condition is detected, the controller 16 executes a potential draw  
5 occlusion condition function (in shorthand, the "Potential Occlusion Function"). The Potential Occlusion Function first suspends the draw for a period of time (e.g. upwards to 20 seconds, and desirably about 10 seconds) to rest the vein. While the vein rests, the  
10 controller 16 also increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg), unless cuff pressure, when adjusted, exceeds a prescribed maximum (e.g., upwards to 100 mmHg, desirably about 70 mmHg). If the prescribed  
15 maximum cuff pressure condition exists, no incremental changes to the cuff pressure are made during the prescribed vein rest interval.

After the prescribed vein rest interval, the Potential Occlusion Function resets the attempted pump  
20 stroke counter to zero and resumes the draw cycle. The controller 16 monitors the initial series of consecutive pump strokes during the resumed draw cycle, up to a first threshold number of pump strokes (e.g., 5). The magnitude of the first threshold number is larger than the number  
25 of consecutive incomplete fill donor pump strokes (i.e., 3) that indicate a potential donor draw occlusion condition. The magnitude of the first threshold number is selected to accurately assess, after a potential donor draw occlusion condition arises, whether a true donor draw  
30 occlusion exists. In the illustrated embodiment, if within the first five pump strokes (or whatever the first threshold number is), three consecutive incomplete fill donor pump strokes take place, the controller 16 assumes that a true donor draw occlusion exists, and thus  
35 generates an occlusion alarm. With the generation of an

occlusion alarm, the controller 16 suspends processing, until the operator can establish that it is safe to resume.

5 If within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes do not take place, the controller 16 assumes that a true vein occlusion may not exist, and that the potential occluded flow condition was either transient, or at least capable of correction short of suspending the procedure. In this event, the Potential Occlusion Function allows the resumed draw cycle to continue beyond 10 the first threshold number of pump strokes up to a second threshold number of pump strokes (e.g., 20 to 100, and desirable about 50).

15 If at any time between the first threshold number of pump strokes and the second threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the Potential Occlusion Function institutes another vein rest interval(e.g. upwards to 20 20 seconds, and desirably about 10 seconds). While the vein rests, the Potential Occlusion Function also again increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg). While the vein rests, the Potential Occlusion 25 Function also lowers the draw rate by a preset decrement (e.g., upwards to 20 ml/min, and desirably about 10 ml/min). If the draw rate, when lowered, is less than a prescribed minimum draw rate (e.g., 70 to 90 ml/min), the controller 16 generates an occlusion alarm. Otherwise, 30 the Potential Occlusion Function resets the attempted pump stroke counter to zero, and resumes the draw cycle at the increased cuff pressure and decreased draw rate.

The controller 16 again monitors the initial series of consecutive pump strokes during the resumed draw 35 cycle, up to the first threshold number of pump strokes



(e.g., 5). If within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the controller 16 assumes that a true donor draw occlusion exists, and thus generates an  
5 occlusion alarm and also suspends processing.

However, if within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes do not take place, the controller 16 allows the resumed draw cycle to continue beyond the first  
10 threshold number of pump strokes up to the second threshold number of pump strokes (e.g., 20 to 100, and desirable about 50). If at any time between the first threshold number of pump strokes and the second threshold number of pump strokes, three consecutive incomplete fill  
15 donor pump strokes take place, the Potential Occlusion Function again institutes another vein rest interval (e.g. upwards to 20 seconds, and desirably about 10 seconds). While the vein rests, the Potential Occlusion Function also again increases the pressure cuff pressure by a  
20 preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg). While the vein rests, the Potential Occlusion Function also again lowers the draw rate by a preset decrement (e.g., upwards to 20 ml/min, and desirably about 10 ml/min), unless the draw rate, when  
25 lowered, is less than a prescribed minimum draw rate (e.g., 70 to 90 ml/min), in which case the controller 16 generates an occlusion alarm. Otherwise, the Potential Occlusion Function resets the attempted pump stroke counter to zero, and resumes the draw cycle at the  
30 increased cuff pressure and decreased draw rate.

The controller 16 continues to repeat the steps of the Potential Occlusion Function, using the first and second pump stroke number thresholds to gage whether a true vein occlusion exists, and either generating an  
35 occlusion alarm if it does, or continuing to attempt

remedial action (by increasing cuff pressure and/or decreasing draw rate), or cancelling the potential donor draw occlusion condition when three consecutive incomplete fill donor pump strokes are not observed during either the first or second threshold periods following a potential donor occlusion condition.

If no three consecutive incomplete fill donor pump strokes take place within the second threshold number of strokes following a potential donor draw occlusion condition, the controller 16 assumes that a true vein occlusion does not exist. The draw cycle continues, and the controller 16 continues to count pump strokes. If the prescribed number (e.g., 3) of consecutive incomplete fill donor pump strokes subsequently takes place, the controller 16 assumes that this event is unrelated to any previous occlusion event condition, and generates a new potential donor draw occlusion condition, executing the Potential Occlusion Function from the start.

It should be appreciated that the Potential Occlusion Function, as just described, can be used with any blood processing device that has means for detecting when a draw blood pumping command does not result in blood flow through the pump.

#### C. Blood Processing Cycles

Prior to undertaking the double unit red blood cell collection procedure, as well as any blood collection procedure, the controller 16 conducts an appropriate integrity check of the cassette 28, to determine whether there are any leaks in the cassette 28. Once the cassette integrity check is complete and no leaks are found, the controller 16 begins the desired blood collection procedure.

In general, using the processing chamber shown in Fig. 9), whole blood is introduced into and separated within the processing chamber 18 as it rotates. As the

processing chamber 18 rotates (arrow R in Fig. 9), the umbilicus 296 conveys whole blood into the channel 126 through the passage 146. The whole blood flows in the channel 126 in the same direction as rotation (which is counterclockwise in Fig. 9). Alternatively, the chamber 18 can be rotated in a direction opposite to the circumferential flow of whole blood, i.e., clockwise, but rotation in the same direction as circumferential blood flow is preferred.

10       The whole blood separates as a result of centrifugal forces. Red blood cells are driven toward the high-G wall 124, while lighter plasma constituent is displaced toward the low-G wall 122. In this flow pattern, a dam 384 projects into the channel 126 toward the high-G wall 124. The dam 384 prevents passage of plasma, while allowing passage of red blood cells into a channel 386 recessed in the high-G wall 124. The channel 386 directs the red blood cells into the umbilicus 296 through the radial passage 144. The plasma constituent is conveyed from the channel 126 through the radial passage 142 into umbilicus 296.

#### 1. Collection Cycle

During a typical collection cycle of the double unit red blood cell collection procedure, whole blood drawn from the donor is processed to collect two units of red blood cells, while returning plasma to the donor. The donor interface pumps PP3/PP4 in the cassette, the anticoagulant pump P5 in the cassette, the in-process pump PP1 in the cassette, and the plasma pump PP2 in the cassette are pneumatically driven by the controller 16, in conjunction with associated pneumatic valves, to draw anticoagulated blood into the in-process container 312, while conveying the blood from the in-process container 312 into the processing chamber 18 for separation. This arrangement also removes plasma from the processing

chamber into the plasma container 304, while removing red blood cells from the processing chamber into the red blood cell container 308. This phase continues until an incremental volume of plasma is collected in the plasma collection container 304 (as monitored by a weigh sensor) or until a targeted volume of red blood cells is collected in the red blood cell collection container (as monitored by a weigh sensor).

If the volume of whole blood in the in-process container 312 reaches a predetermined maximum threshold before the targeted volume of either plasma or red blood cells is collected, the controller 16 terminates operation of the donor interface pumps PP3/PP4 to terminate collection of whole blood in the in-process container 312, while still continuing blood separation. If the volume of whole blood reaches a predetermined minimum threshold in the in-process container 312 during blood separation, but before the targeted volume of either plasma or red blood cells is collected, the controller 16 returns to drawing whole blood to thereby allow whole blood to enter the in-process container 312. The controller toggles between these two conditions according to the high and low volume thresholds for the in-process container 312, until the requisite volume of plasma has been collected, or until the target volume of red blood cells has been collected, whichever occurs first.

## 2. Return Cycle

During a typical return cycle (when the targeted volume of red blood cells has not been collected), the controller 16 operates the donor interface pumps PP3/PP4 within the cassette 28, the in-process pump PP1 within the cassette, and the plasma pump PP2 within the cassette, in conjunction with associated pneumatic valves, to convey anticoagulated whole blood from the in-

process container 312 into the processing chamber 18 for separation, while removing plasma into the plasma container 304 and red blood cells into the red blood cell container 308. This arrangement also conveys plasma from the plasma container 304 to the donor, while also mixing saline from the container 288 in line with the returned plasma. The in line mixing of saline with plasma raises the saline temperature and improves donor comfort. This phase continues until the plasma container 304 is empty, as monitored by the weigh sensor.

If the volume of whole blood in the in-process container 312 reaches a specified low threshold before the plasma container 304 empties, the controller 16 terminates operation of the in-process pump PP1 to terminate blood separation. The phase continues until the plasma container 304 empties.

Upon emptying the plasma container 304, the controller 16 conducts another collection cycle. The controller 16 operates in successive collection and return cycles until the weigh sensor indicates that a desired volume of red blood cells have been collected in the red blood cell collection container 308. The controller 16 terminates the supply and removal of blood to and from the processing chamber, while operating the donor interface pumps PP3/PP4 in the cassette 28 to convey plasma remaining in the plasma container 304 to the donor. The controller 16 next operates the donor interface pumps PP3/PP4 in the cassette to convey the blood contents remaining in the in-process container 312 to the donor as well as convey saline to the donor, until a prescribed replacement volume amount is infused, as monitored by a weigh sensor.

### 3. . In-Line Leukofiltration Cycle

When the collection of red blood cells and the return of plasma and residual blood components has been

- 37 -

completed, the controller 16 switches, either automatically or after prompting the operator, to an in-line leukofiltration cycle. During this cycle, red blood cells are removed from the red blood cell collection reservoir 308 and conveyed into the red blood cell storage containers 307 and 308 through the leukocyte removal filter 313. At the same time, a desired volume of red blood cell storage solution from the container 208 is mixed with the red blood cells.

10 In the first stage of this cycle, the controller 16 operates donor interface pumps PP3/PP4 in the cassette to draw air from the red blood cell storage containers 307 and 309, the filter 313, and the line 311, and to transfer this air into the red blood cell collection reservoir 308. This stage minimizes the volume of air residing in the red blood cell storage containers 307 and 309 before the leukocyte removal process begins. The stage also provides a volume of air in the red blood cell collection container 308 that can be used purge red blood cells from the filter 313 into the red blood cell collection containers 307 and 309 once the leukocyte removal process is completed.

25 In the next stage, the controller 16 operates the donor interface pumps PP3/PP4 in the cassette 28 to draw a priming volume of storage solution from the solution container 208 into the red blood cell collection reservoir 308. This stage primes the tubing 278 between the container 208 and the cassette 28, to minimize the volume of air pumped into the final red blood cell storage containers 307 and 309.

30 In the next stage, the controller 16 operates the donor interface pumps PP3/PP4 in the cassette 28 to alternate pumping red blood cells from the red blood cell collection reservoir 308 into the red blood cell collection containers 307 and 309 (through the filter

35

313), with pumping of red blood cell storage solution from the container 208 into the red blood cell collection containers 307 and 309 (also through the filter 313). This alternating process mixes the storage solution with  
5 the red blood cells. The controller 16 counts the pneumatic pump strokes for red blood cells and the storage solution to obtain a desired ratio of red cell volume to storage solution volume (e.g., five pump strokes for red blood cells, followed by two pump strokes  
10 for storage solution, and repeating the alternating sequence). This alternating supply of red blood cells and storage solution continues until the weigh scale for the red blood cell collection reservoir 308 indicates that the reservoir 308 is empty.

15 When the red blood cell collection reservoir 308 is empty, the controller 16 operates the donor interface pumps PP3/PP4 to pump additional storage solution through the filter 313 and into the red blood storage containers 307 and 309, to ensure that a desired ratio between  
20 storage solution volume and red blood cell volume exists.

This also rinses residual red blood cells from the filter 313 into the red blood cell storage containers 307 and 309 to maximize post-filtration percent red blood cell recovery.

25 The controlled ratio of pump strokes for red blood cells and for storage solution that the controller 16 achieves ensures that the storage solution is always metered in at a constant ratio. Therefore, regardless of the volume of red blood cells collected, the final red  
30 blood cell / storage solution hematocrit can be constant.

The alternating supply of red blood cells and storage solution through the filter 313 eliminates the need to first drain the storage solution into the red blood cell collection reservoir 308, which lessens the  
35 overall procedure time.

The alternating supply of red blood cells and storage solution through the filter 313 also eliminates the need to manually agitate a red blood cell / storage solution mixture prior to leukofiltration. Due to  
5 density differences, when concentrated red blood cells are added to a preservation solution, or vice versa, the preservation solution floats to the top. Poorly mixed, high hematocrit, high viscosity red blood cells lead to reduced flow rates during leukofiltration. Poorly mixed,  
10 high hematocrit, high viscosity red blood cell conditions can also lead to hemolysis. By alternating passage of red blood cells and storage solution through the filter 313, mixing occurs automatically without operator involvement.

15 The alternating supply of red blood cells and storage solution through the filter 313 also eliminates the need to gravity drain the red blood cell product through the leukofilter 313. As a result, filtration can occur in about half the time required for a gravity-drain  
20 procedure.

If desired, the controller 16 can monitor weight changes relating to the red blood cell collection reservoir 308 and the red blood cell storage containers 307 and 309, to derive a value reflecting the percent of  
25 red blood cells that are recovered after passage through the leukofilter 313. This value can be communicated to the operator, e.g., on the display screen of user the user interface.

The following expression can be used to derive the  
30 percent recovery value:

$$\% \text{ Recovery} = [( \text{Bag A Vol} + \text{Bag B Vol} ) / \text{RBC Vol} + \text{Adsol} ] * 100$$

where:

Bag A Vol represents the volume of red blood cells  
35 collected the container 307, calculated as follows:



(Wt of Container 307 containing red blood cells(in  
g) - Container 307 Tare)/ 1.062 g/ml

Bag B Vol represents the volume of red blood cells  
collected the container 309, calculated as follows:

5 (Wt of Container 309 containing red blood cells(in  
g) - Container 309 Tare)/ 1.062 g/ml

RBC Vol represents the volume of red blood cells  
collected in the red blood cell collection reservoir 308,  
which the controller 16 determines by weight sensing at  
10 the end of the procedure.

Adsol represents the volume of red blood cell  
storage solution added to the during leukofiltration,  
which is determined by the controller 16 by capacitive  
sensing during processing.

15 a. The Leukofilter

The leukofilter 313 can be variously constructed.  
In the embodiment illustrated in Figs. 24A and 24B, the  
filter comprises a housing 100 inclosing a filtration  
medium 102 that can comprise a membrane or be made from a  
20 fibrous material. The filtration medium 102 can be  
arranged in a single layer or in a multiple layer stack.  
If fibrous, the medium 102 can include melt blown or spun  
bonded synthetic fibers (e.g., nylon or polyester or  
polypropylene), semi-synthetic fibers, regenerated  
25 fibers, or inorganic fibers. If fibrous, the medium 102  
removes leukocytes by depth filtration. If a membrane,  
the medium 102 removes leukocytes by exclusion.

The housing 100 can comprise rigid plastic plates  
sealed about their peripheries. In the illustrated  
30 embodiment, the housing 100 comprises first and second  
flexible sheets 104 of medical grade plastic material,  
such as polyvinyl chloride plasticized with di-2-  
ethylhexyl-phthalate (PVC-DEHP). Other medical grade  
plastic materials can be used that are not PVC and/or are  
35 DEHP-free.

In the illustrated embodiment, a unitary, continuous peripheral seal 106 (see Fig. 24B) is formed by the application of pressure and radio frequency heating in a single process to the two sheets 104 and filtration medium 102. The seal 106 joins the two sheets 104 to each other, as well as joins the filtration medium 102 to the two sheets 104. The seal 106 integrates the material of the filtration medium 102 and the material of the plastic sheets 104, for a reliable, robust, leak-proof boundary. Since the seal 106 is unitary and continuous, the possibility of blood shunting around the periphery of the filtration medium 102 is eliminated.

The filter 313 also includes inlet and outlet ports 108. The ports 108 can comprise tubes made of medical grade plastic material, like PVC-DEHP. In the embodiment shown in Fig. 24, the ports 108 comprise separately molded parts that are heat sealed by radio frequency energy over a hole 109 formed in the sheets 104 (see Fig. 24B).

In the illustrated embodiment (as Figs. 25A and 25B show), the filter 313 is desirably placed within a restraining fixture 110 during use. The fixture 110 restrains expansion of the flexible sheets 104 of the filter housing 100 as a result of pressure applied by pumping red blood cells through the filter 313. The fixture 110 keeps the total blood volume in the filter 313 at a minimum through the filtration process, thereby decreasing filtration time, as well as increasing the red blood cell recovery percentage following leukofiltration.

The fixture 110 can take various forms. In the illustrated embodiment, the fixture 110 comprises two plates 112 coupled by a hinge 114. The fixture 110 can be placed in an open condition (as Fig. 25A shows) to receive the filter 313 prior to leukofiltration, or to remove the filter 313 following leukofiltration. The

fixture 110 can also be placed in a closed condition (as Fig. 25B shows) to sandwich the filter 313 between the two plates 112. A releasably latch 116 holds the plates 112 in the closed condition for use.

5       The plates 112 maintain a desired gap clearance, thereby restraining expansion of the filter 313 during use. The gap clearance is selected to maintain a desired blood flow rate at a desired minimum blood volume.

10       The plates 112 desirably include indentations 118 in which the ports 108 of the filter 313 rest in a non-occluded condition when the fixture 110 is closed. The interior surfaces of the plates 112 may be roughed or scored with a finish to aid blood flow through the filter 313 when the fixture 110 is closed.

15       The fixture 110 can be made as a stand-alone item that can be separately stored prior to use. It can be stored in association with the device 14 during transport and prior to use, e.g., in a receptacle 128 formed on the exterior of the lid 40 of the device 14 (see Fig. 26).

20       The fixture 110 can include a mounting bracket 130 (see Fig. 28) that, e.g., slidably engages a mating mounting track 132, to hold the fixture 110 in the receptacle 128 prior to use (shown in phantom lines in Fig. 26) or to secure the fixture 110 on the base 38 as leukofiltration  
25       is carried out (see Fig. 27).

      It should be appreciated that pump-assisted leukofiltration of red blood cells, whole blood, or other blood cell products, wherein blood flow through a leukofilter is not driven strictly by gravity flow, can  
30       be carried out using manual or automated systems having configurations different than those shown in this Specification. For example, external peristaltic or fluid actuated pumping devices can be used to transfer whole blood or manually processed blood products from  
35       separation bags into processing or storage containers

through intermediate leukofiltration devices. It should also be appreciated that a filter restraining fixture of the type shown in Fig. 24B can also be used in association with any pump-assisted leukofiltration system. It should also be appreciated that a filter restraining fixture 110 can also be used in systems where blood flow through the leukofilter relies strictly upon gravity flow.

The many features of the invention have been demonstrated by describing their use in separating whole blood into component parts for storage and blood component therapy. This is because the invention is well adapted for use in carrying out these blood processing procedures. It should be appreciated, however, that the features of the invention equally lend themselves to use in other blood processing procedures.

For example, the systems and methods described, which make use of a programmable cassette in association with a blood processing chamber, can be used for the purpose of washing or salvaging blood cells during surgery, or for the purpose of conducting therapeutic plasma exchange, or in any other procedure where blood is circulated in an extracorporeal path for treatment.

Features of the invention are set forth in the following claims.

We Claim:

1. A blood processing system comprising  
a blood processing set including a source of  
blood cells, and a blood component collection flow  
5 channel coupled to the source of blood cells including a  
blood cell storage container and an in-line filter to  
remove leukocytes from the blood cells before entering  
the blood cell storage container, the in-line filter  
including a fibrous filter medium, first and second  
10 flexible housings, a unitary, continuous peripheral seal  
formed by application of pressure and radio-frequency  
heating in a single process to join the first and second  
flexible housings to each other, as well as join the  
fibrous filtration medium to the first and second  
15 flexible housings, and

a pump station adapted to be placed into  
communication with the blood component collection flow  
channel to pump blood into the blood cell storage  
container through the in-line filter.

20 2. A blood processing system according to  
claim 1

further including a fixture to restrain  
expansion of the first and second filter housings as a  
result of pressure applied during operation of the pump  
25 station.

3. A blood processing system according to  
claim 2

wherein the source of blood cells includes a  
donor flow channel including a blood separation device to  
30 separate blood cells from donor whole blood.

4. A blood processing system according to  
claim 1

wherein the source of blood cells includes a  
donor flow channel including a blood separation device to  
35 separate blood cells from donor whole blood.

5. A system according to claim 1 or 2 or 3  
or 4

wherein the controller includes a function to  
derive a value reflecting volume of blood cells present  
5 in the blood cell storage container after passage through  
the filter as a percentage of volume of blood cells  
conveyed to the filter.

6. A system according to claim 1 or 2 or 3  
or 4

10 wherein the pump station includes a fluid  
pressure actuated pump and an actuator to apply fluid  
pressure to the pump.

7. A system according to claim 1 or 2 or 3  
or 4

15 wherein the blood cells comprise red blood  
cells.

8. A method of processing blood comprising  
using the blood processing system as defined in claim 1  
or 2 or 3 or 4.

**ABSTRACT**

Systems and methods separate pump the blood cells through an in-line leukofilter to a blood cell storage container. The leukofilter has a filtration medium enclosed within a flexile housing. The systems and methods can employ a fixture to restrain expansion of the flexible filter housing during operation of the pump.

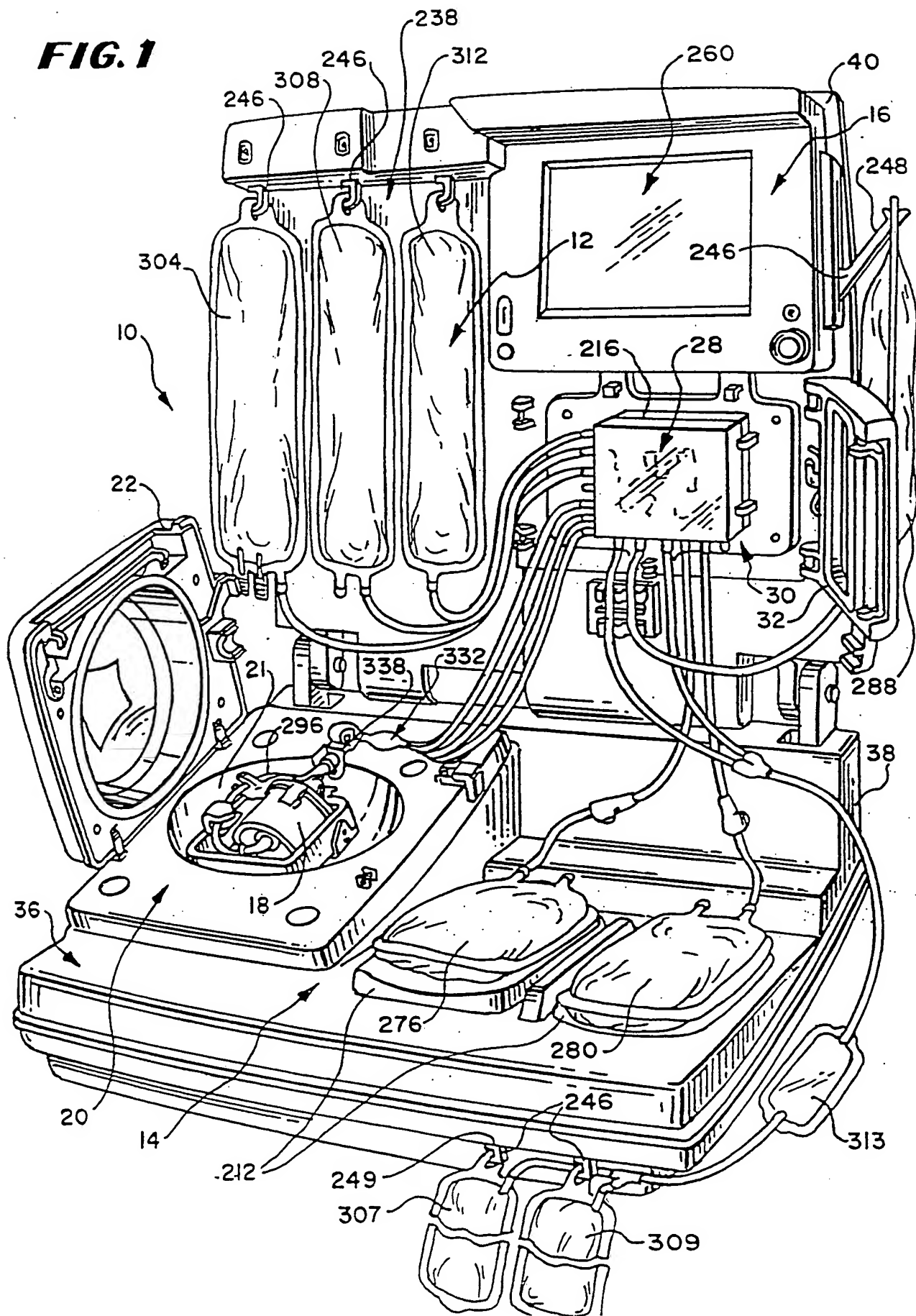
**FIG. 1**



FIG. 2

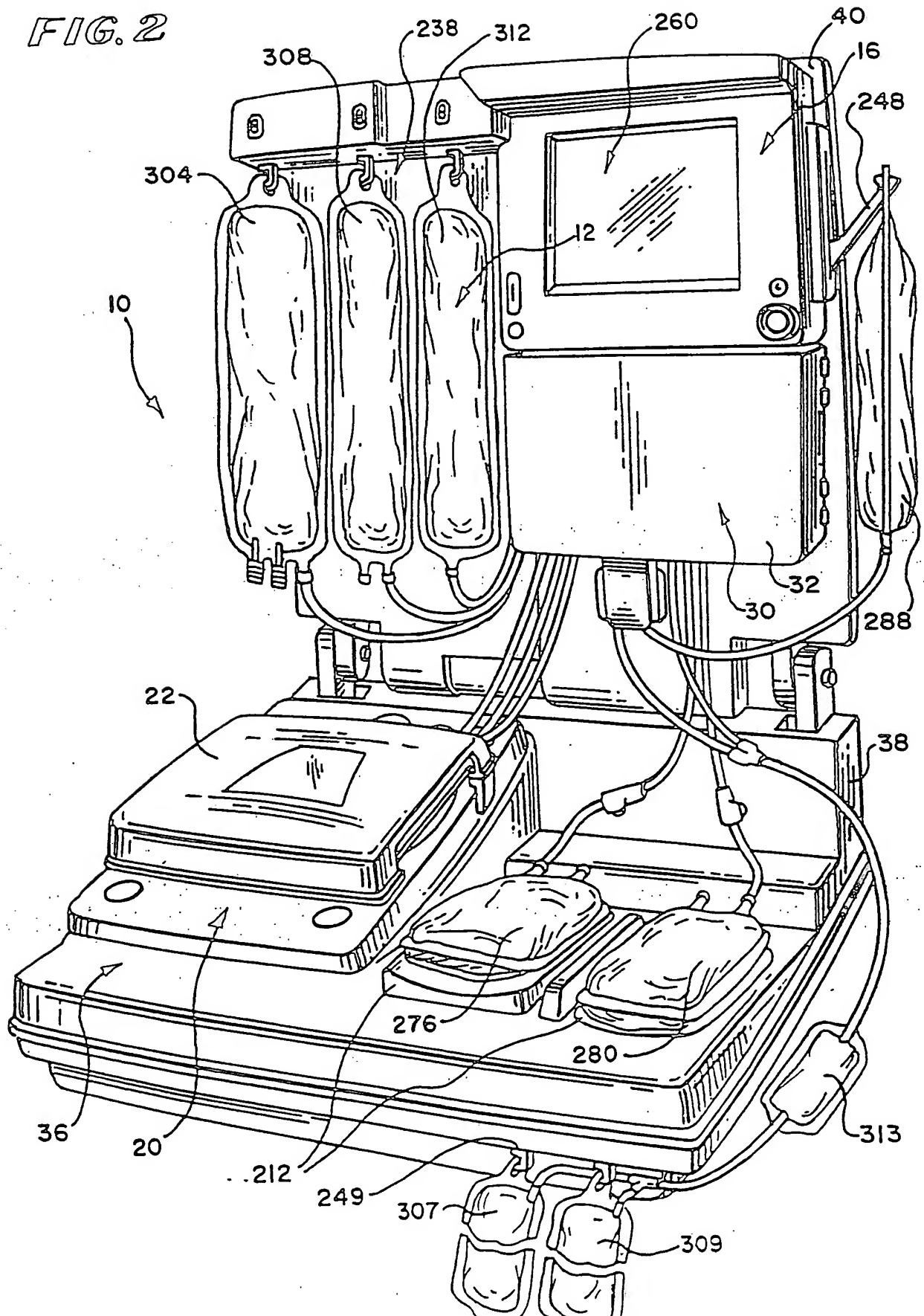
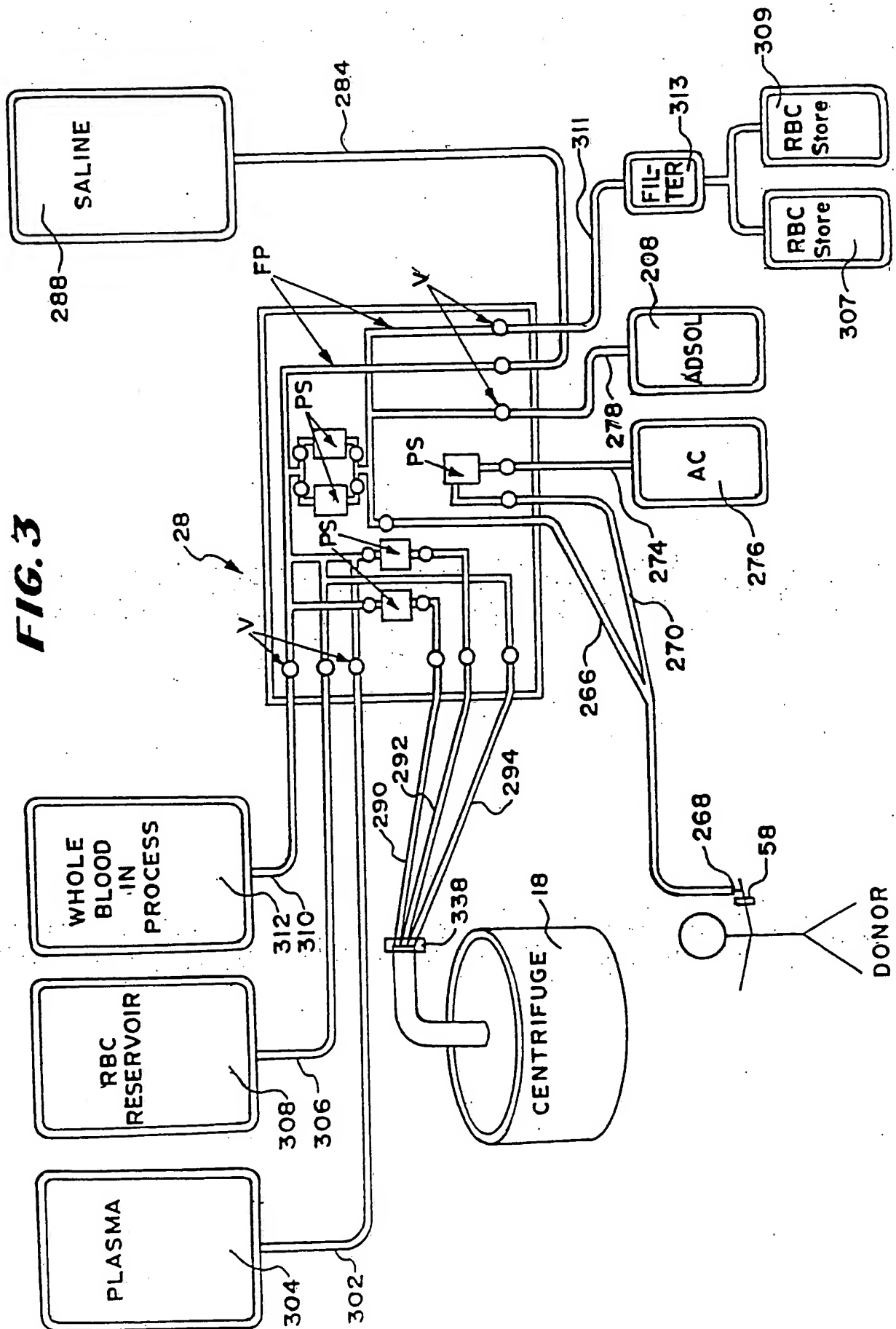
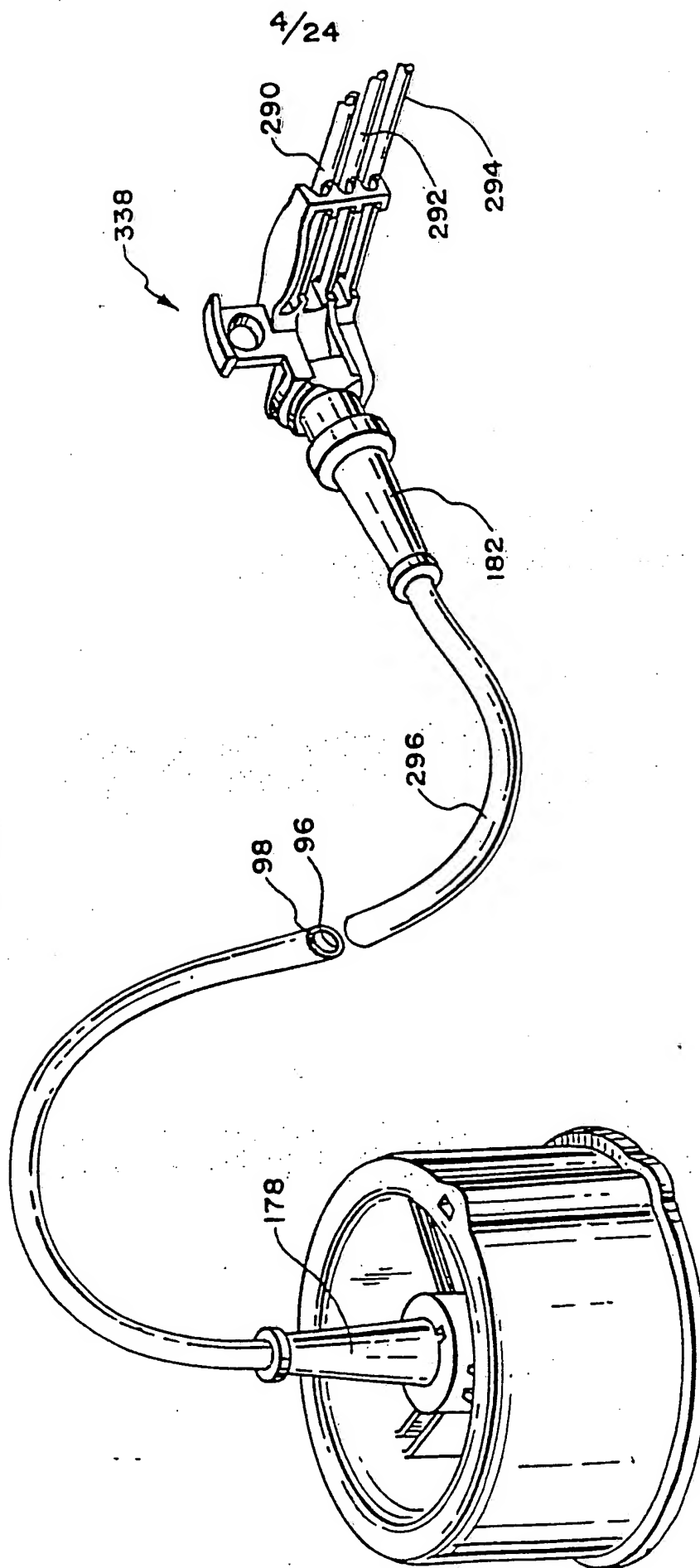
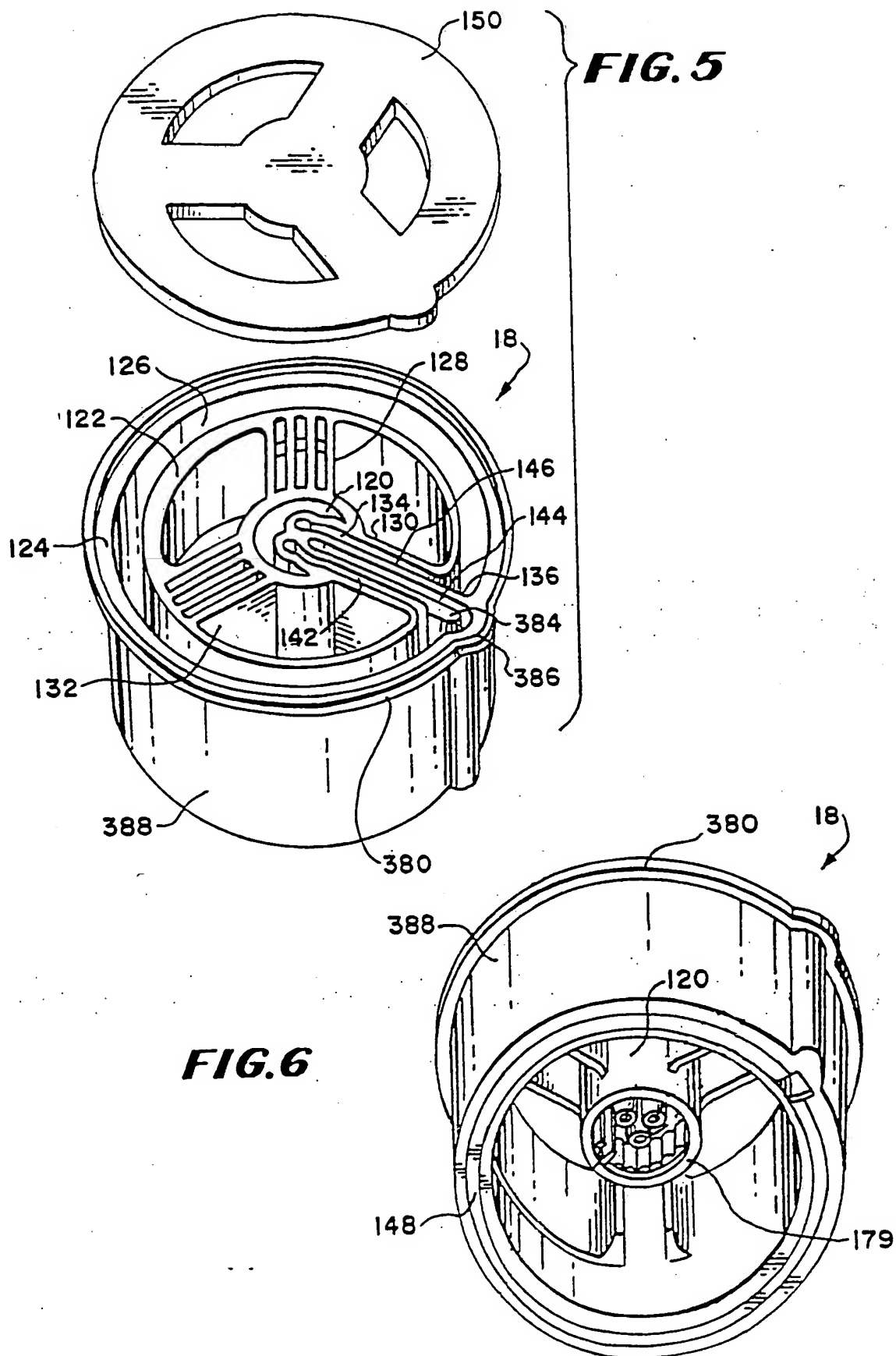


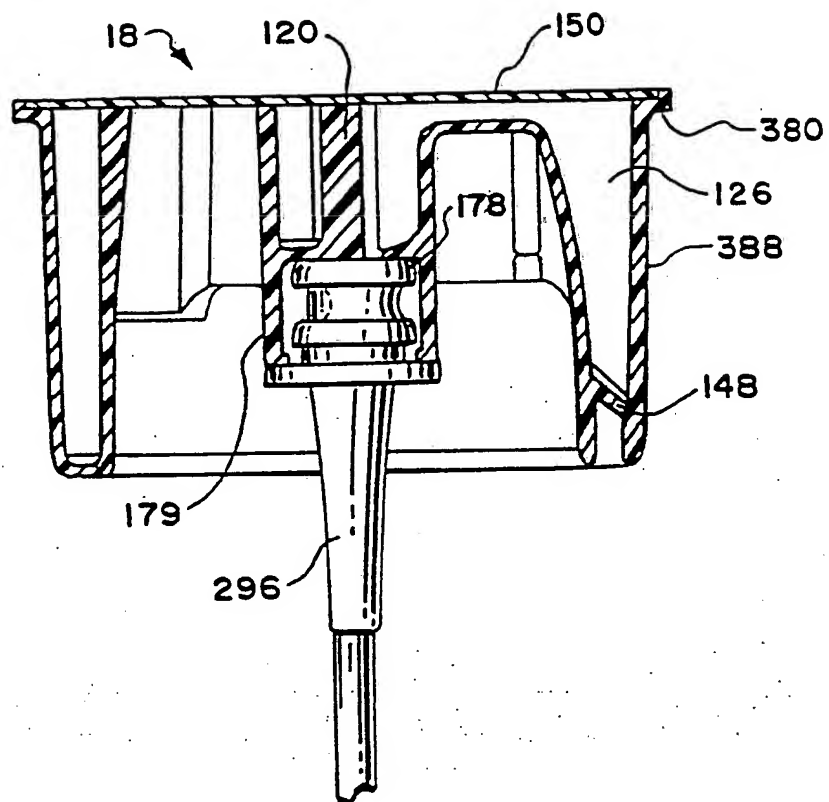
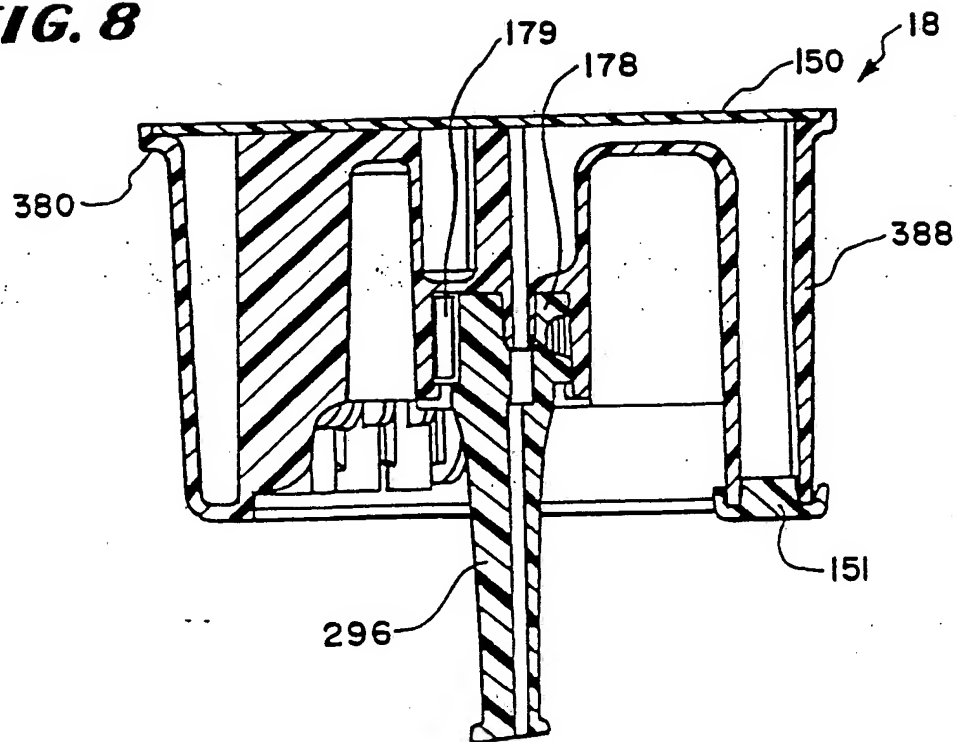
FIG. 3



**FIG. 4**

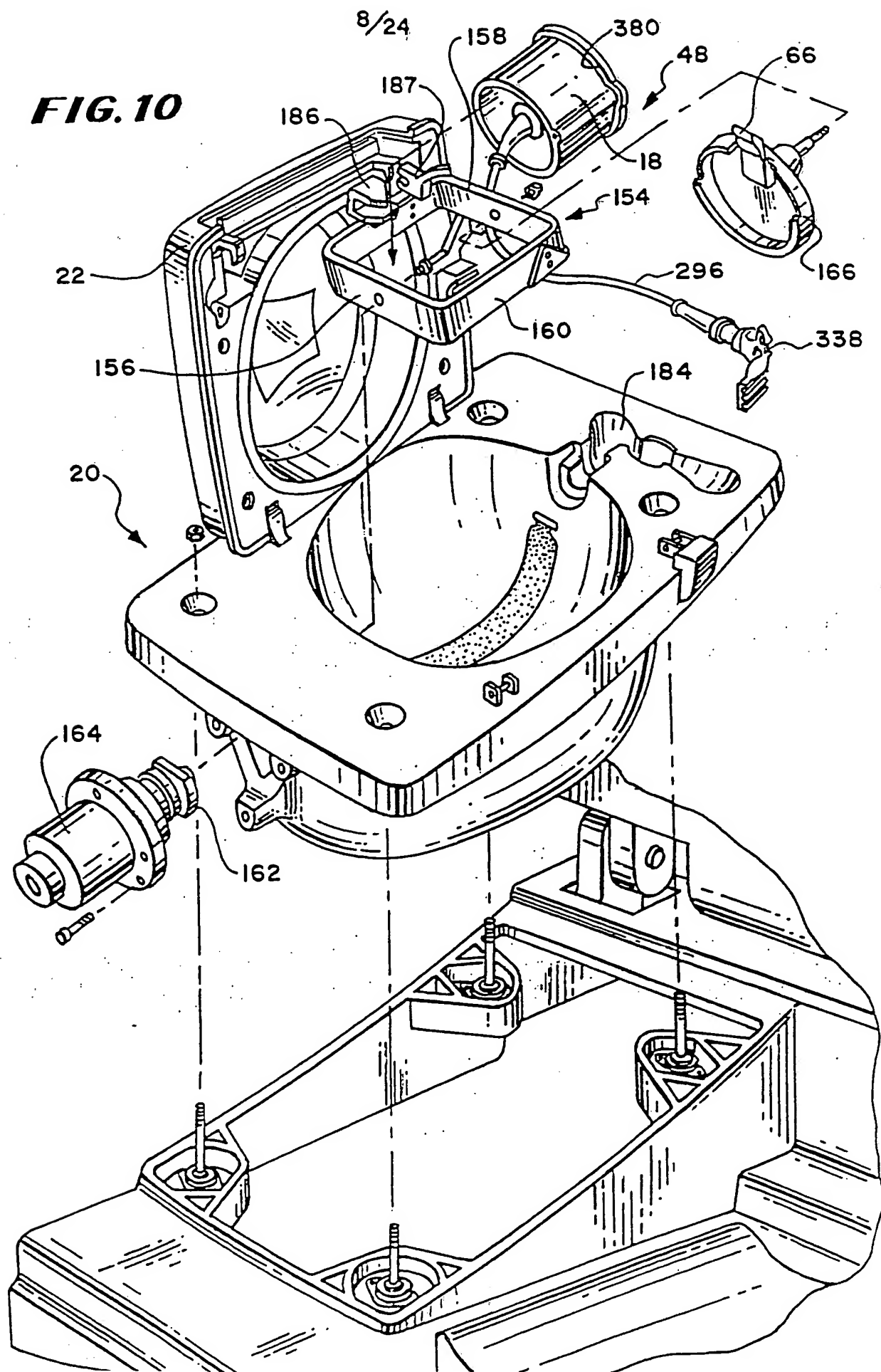




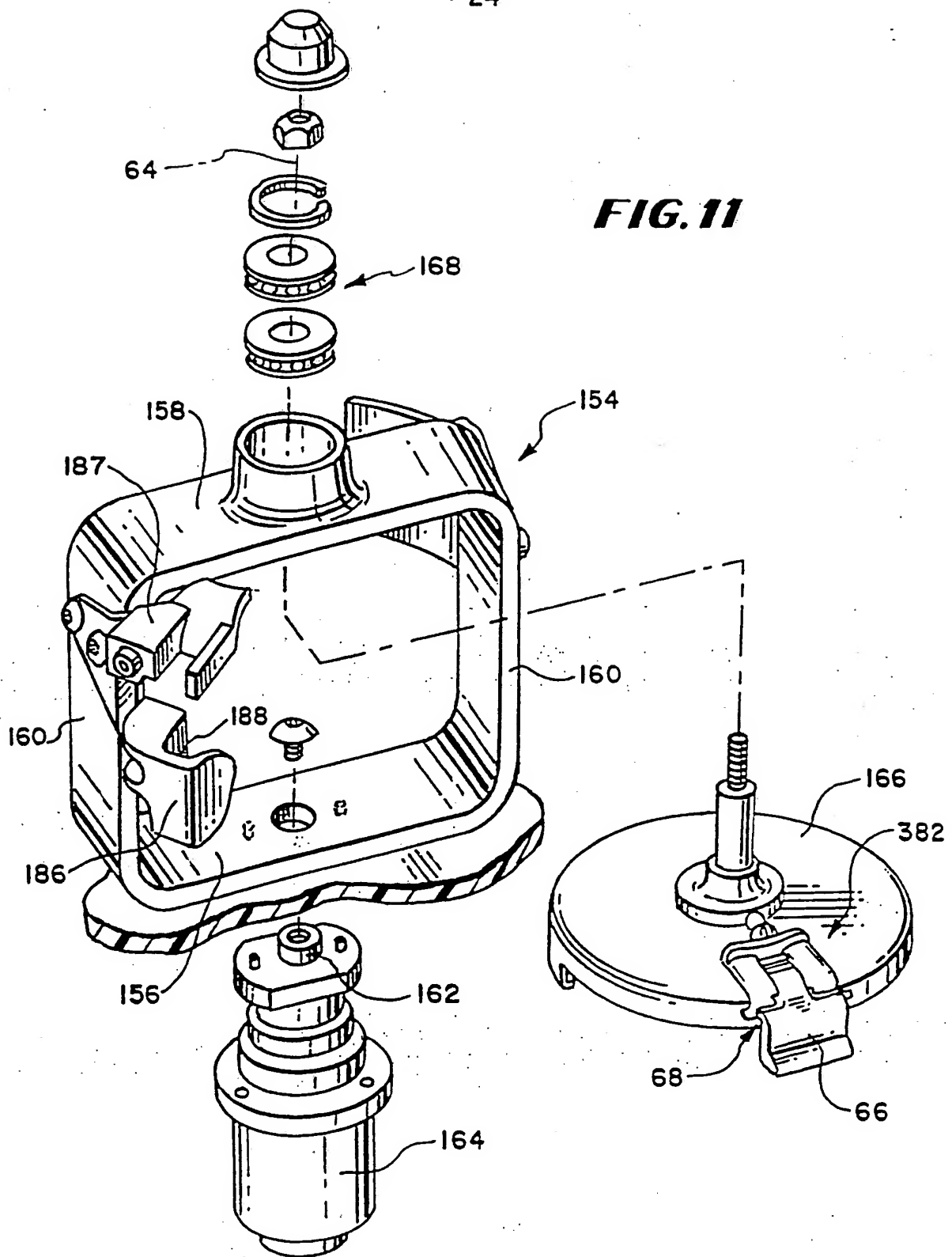
**FIG. 7****FIG. 8**



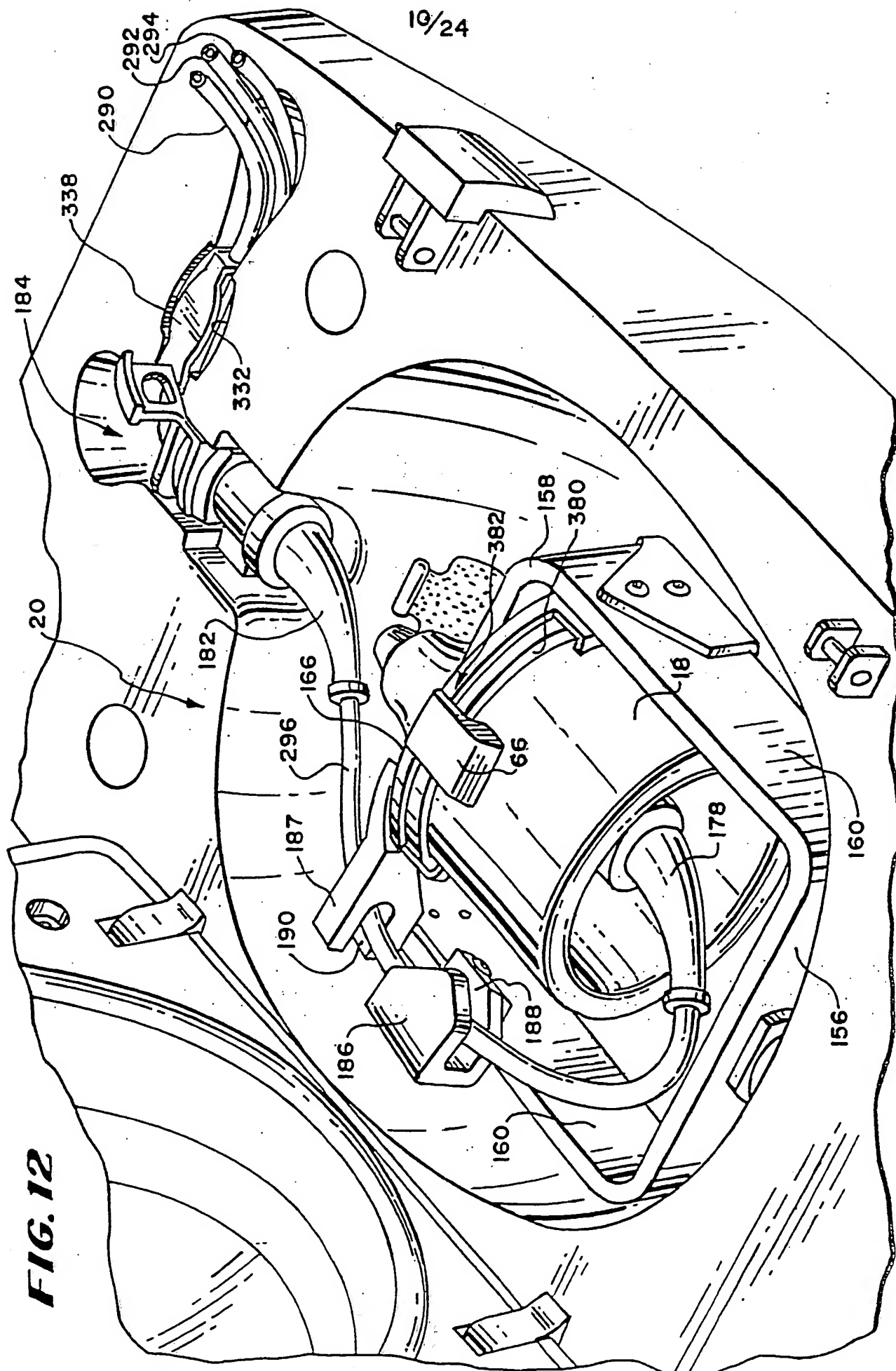
**FIG. 10**



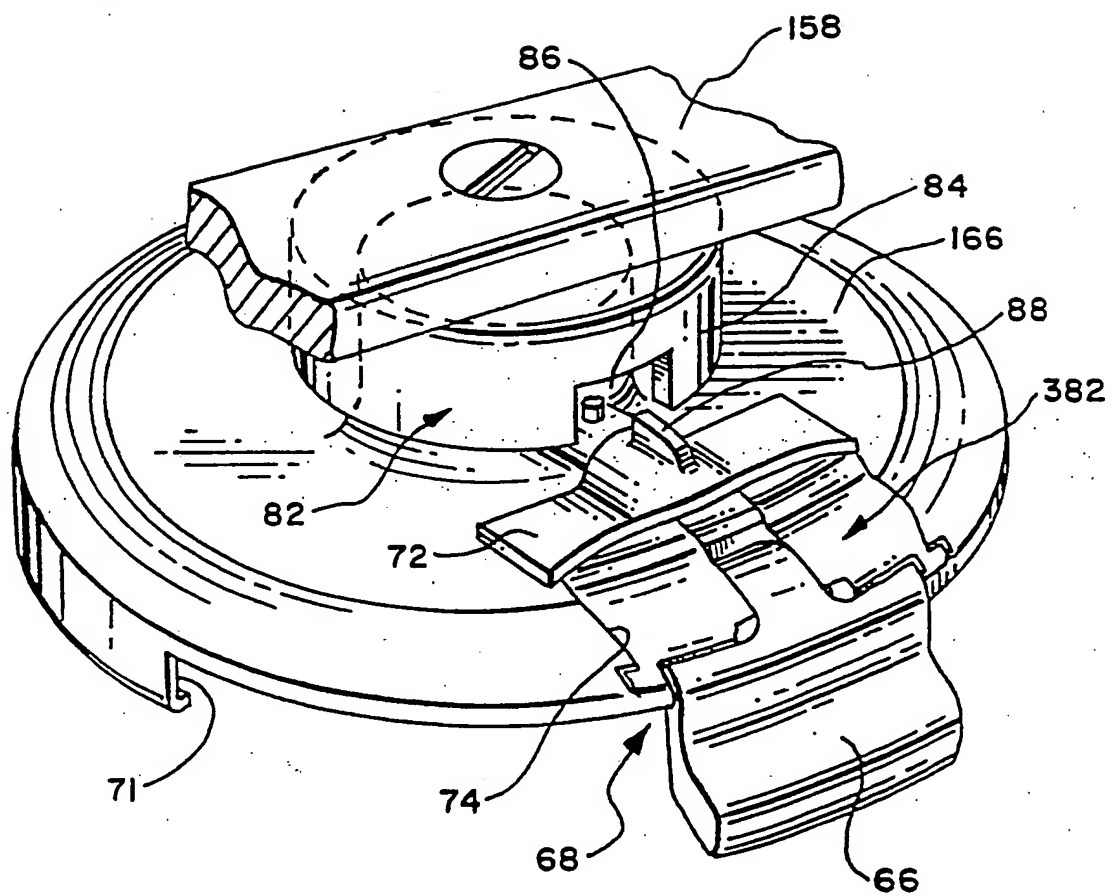
9/24



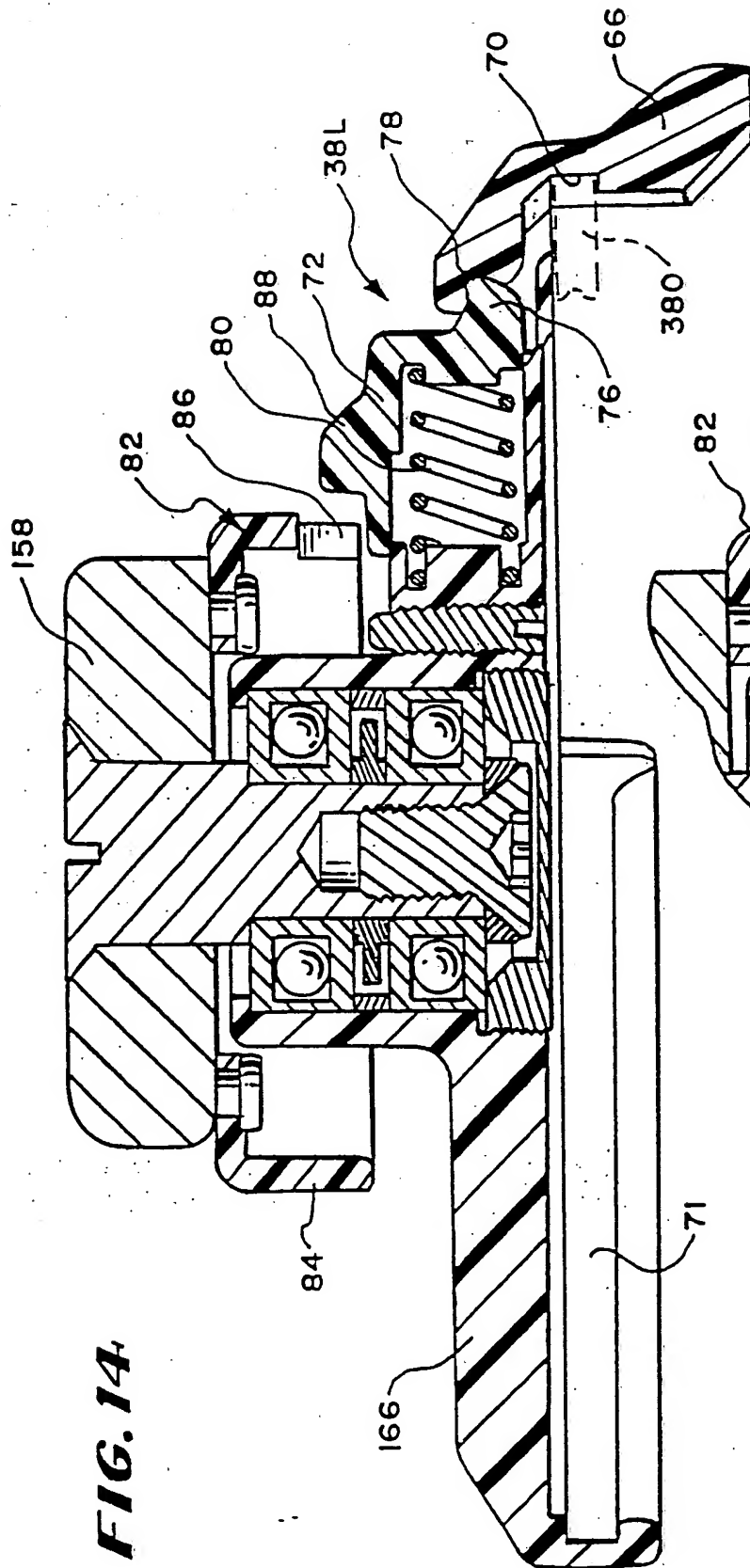




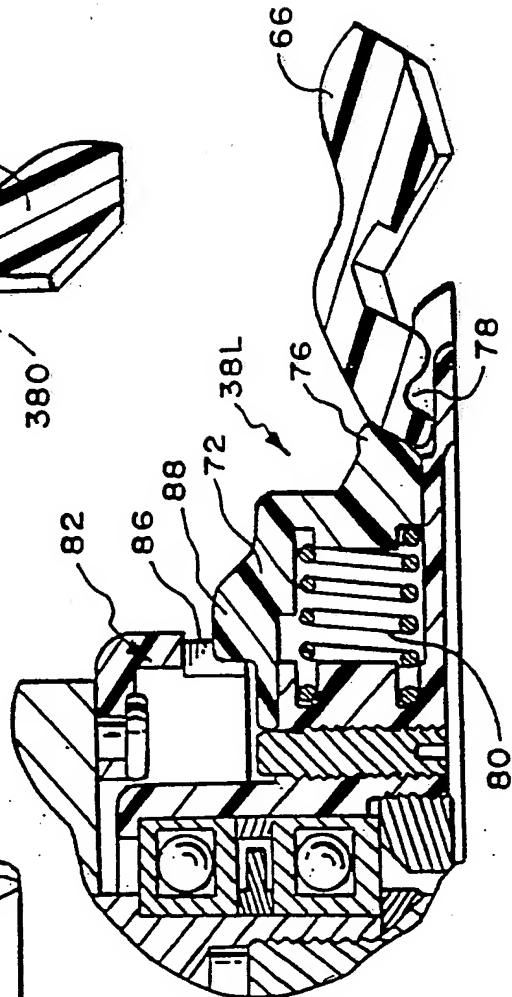
**FIG. 12**

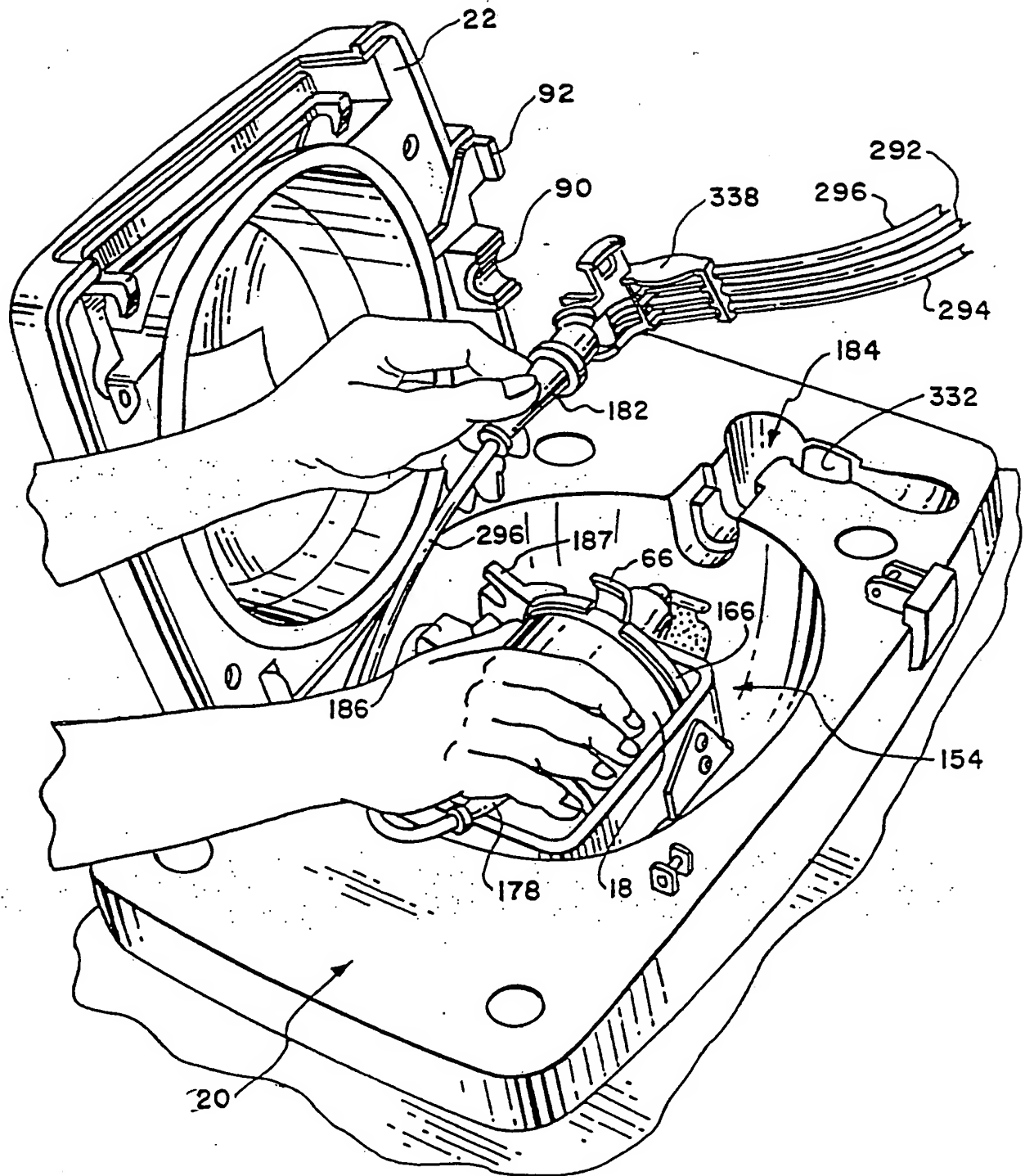
**FIG. 13**

**FIG. 14**

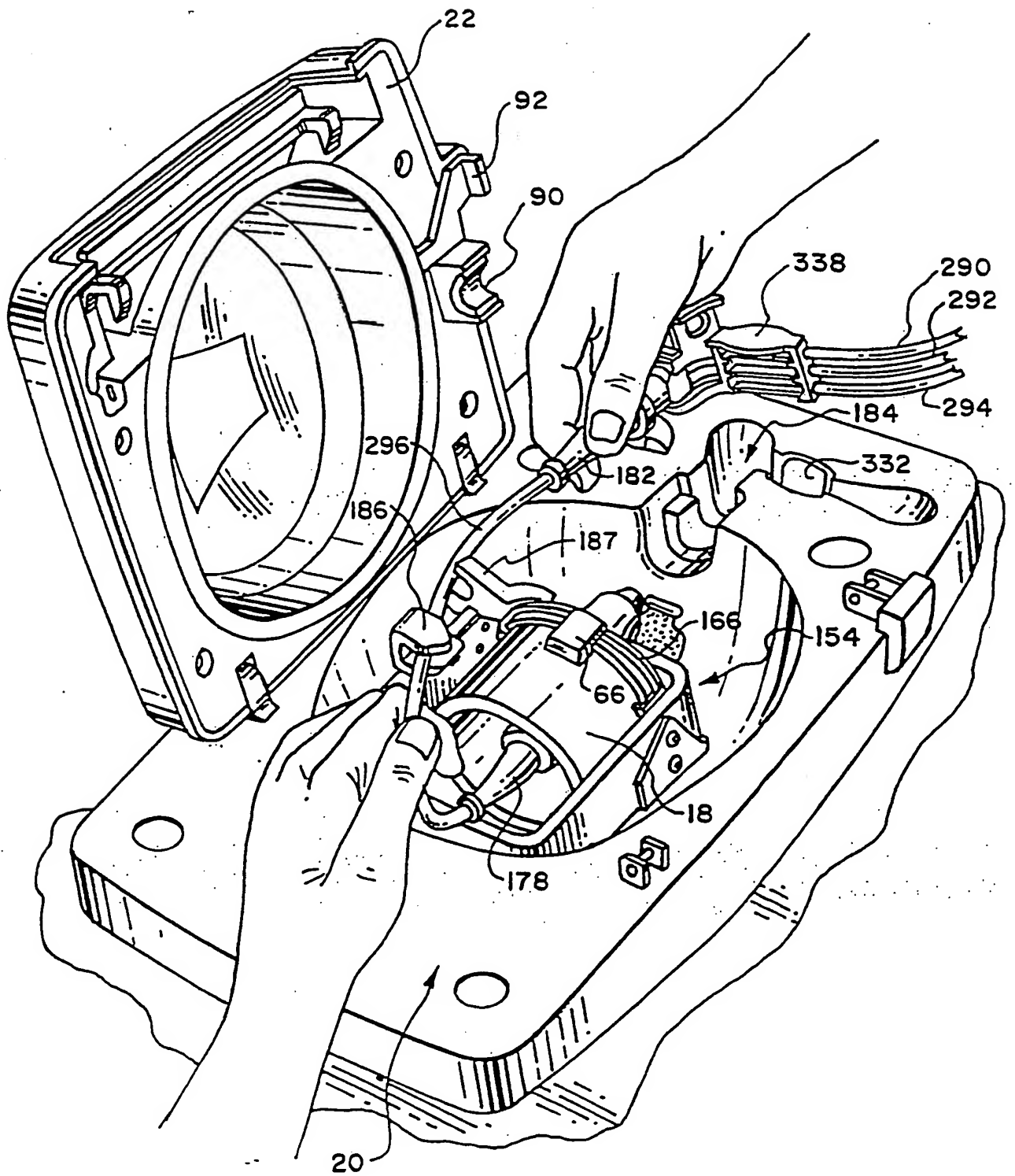


**FIG. 15**

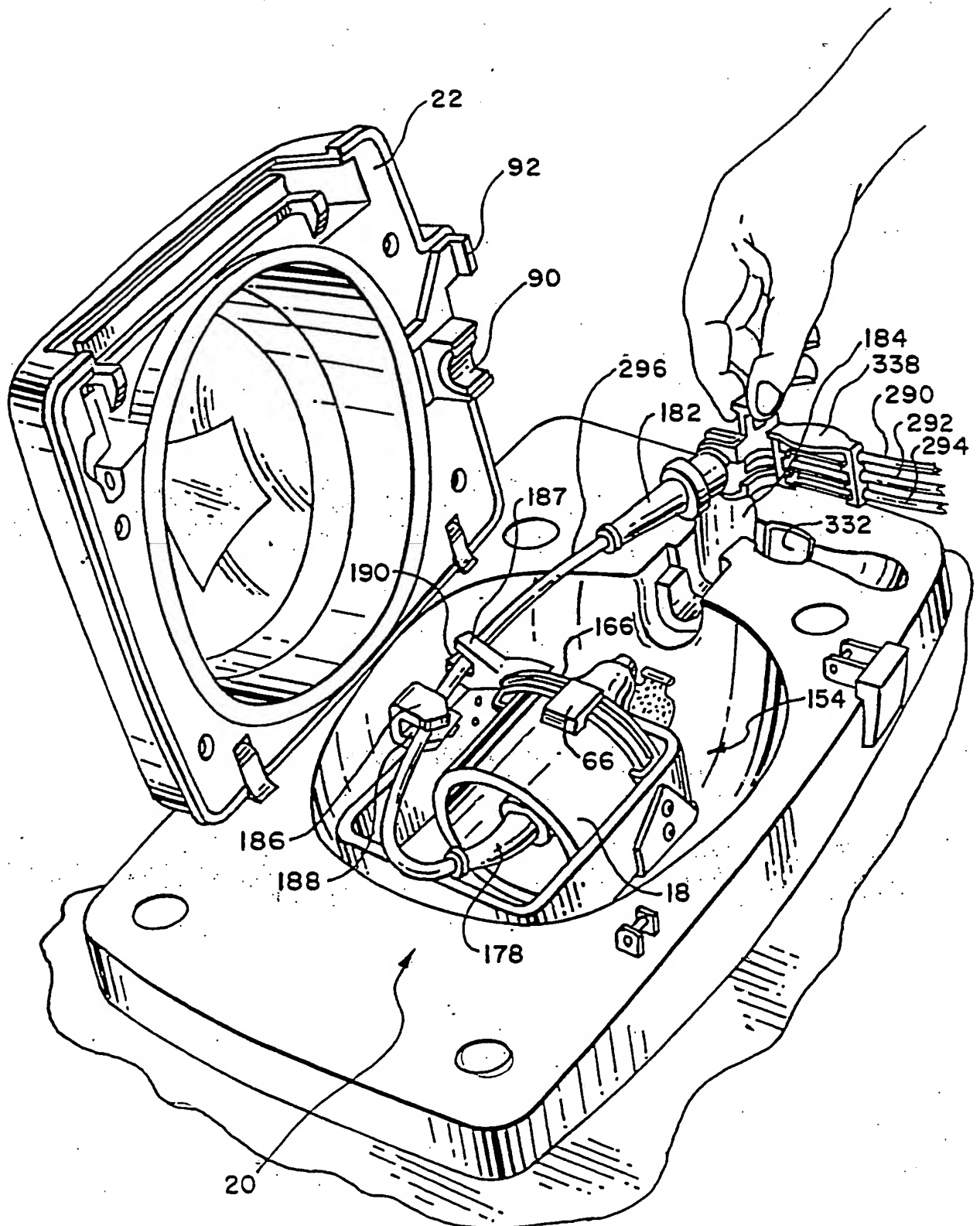


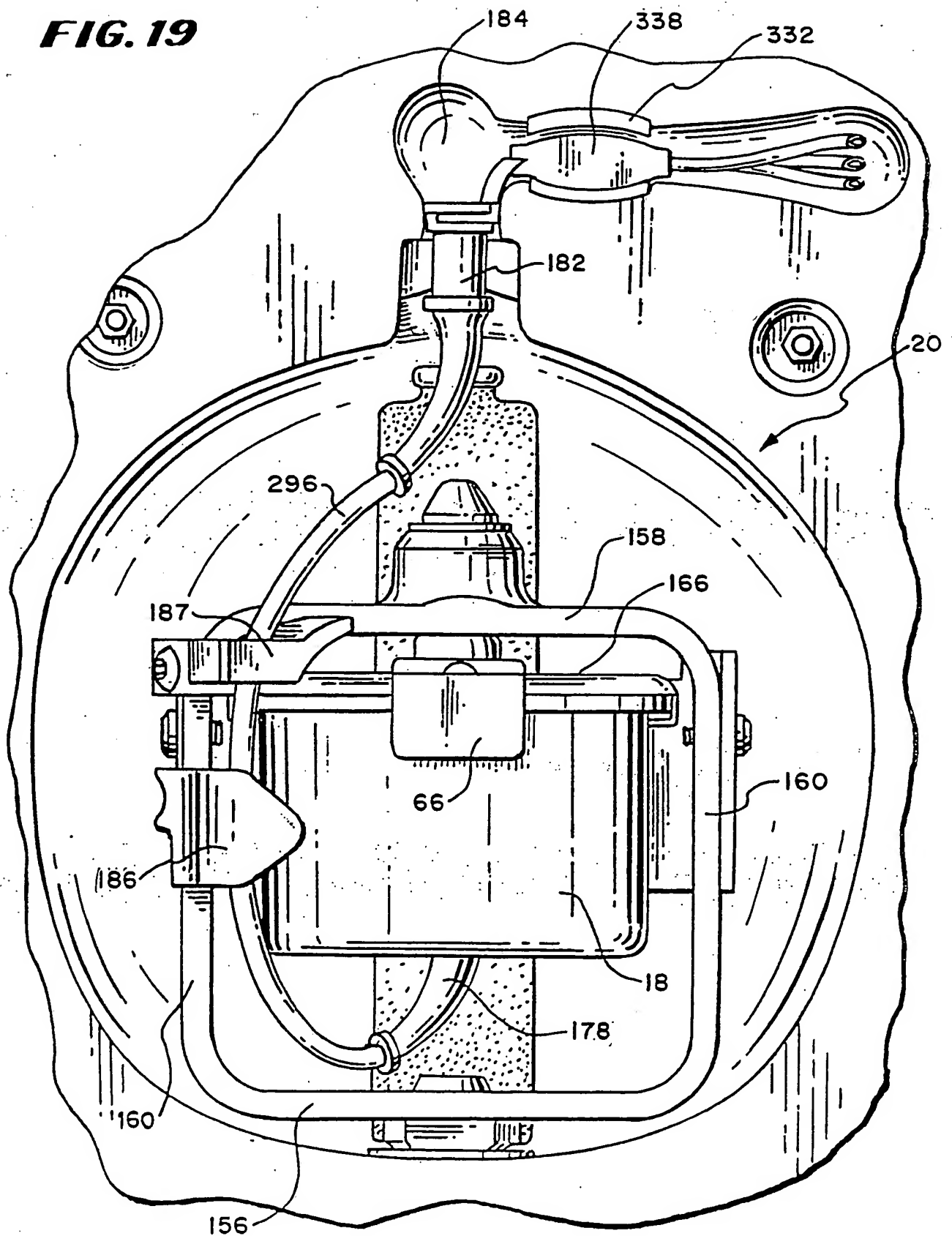
**FIG. 16**

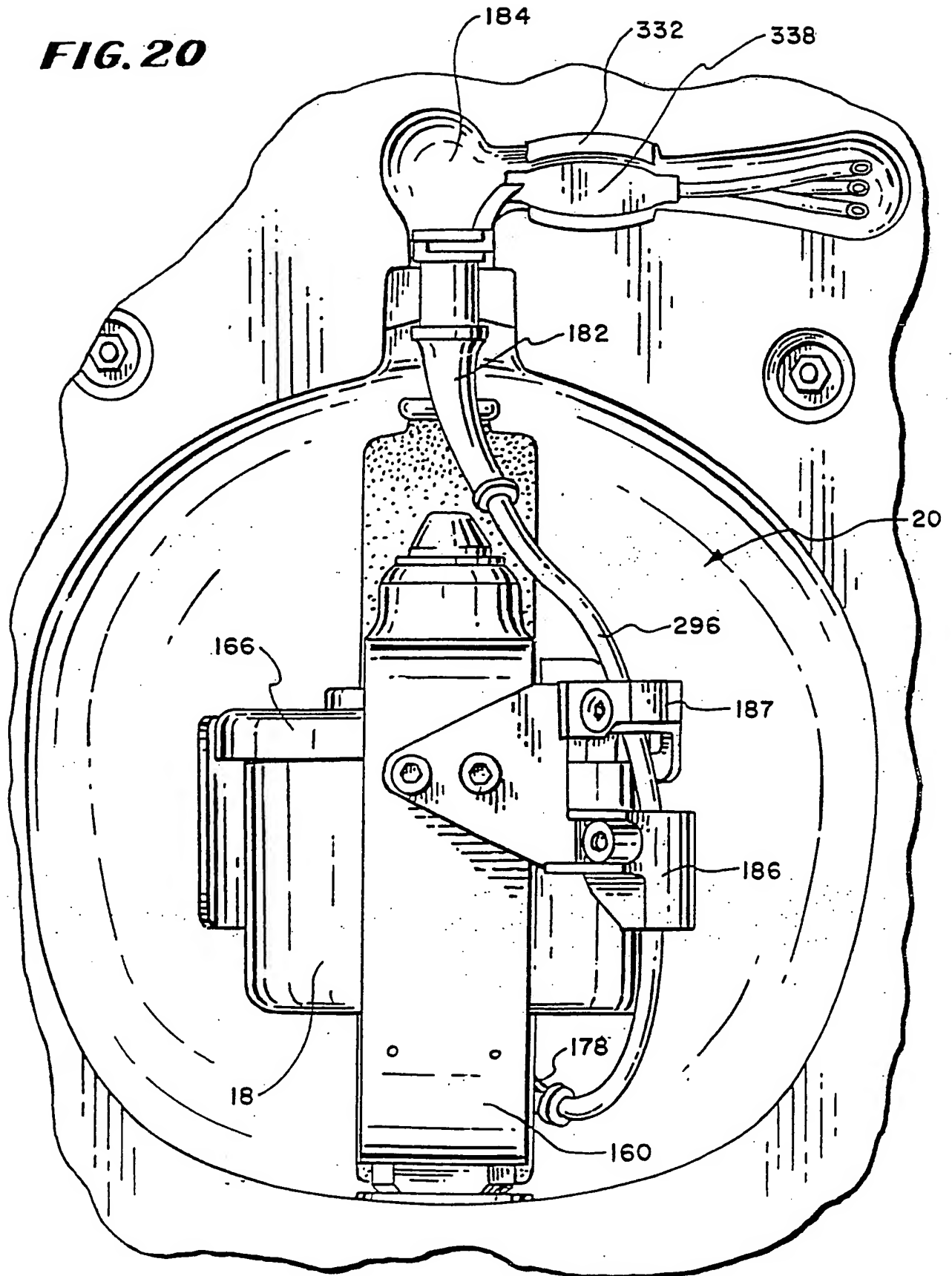
**FIG. 17**



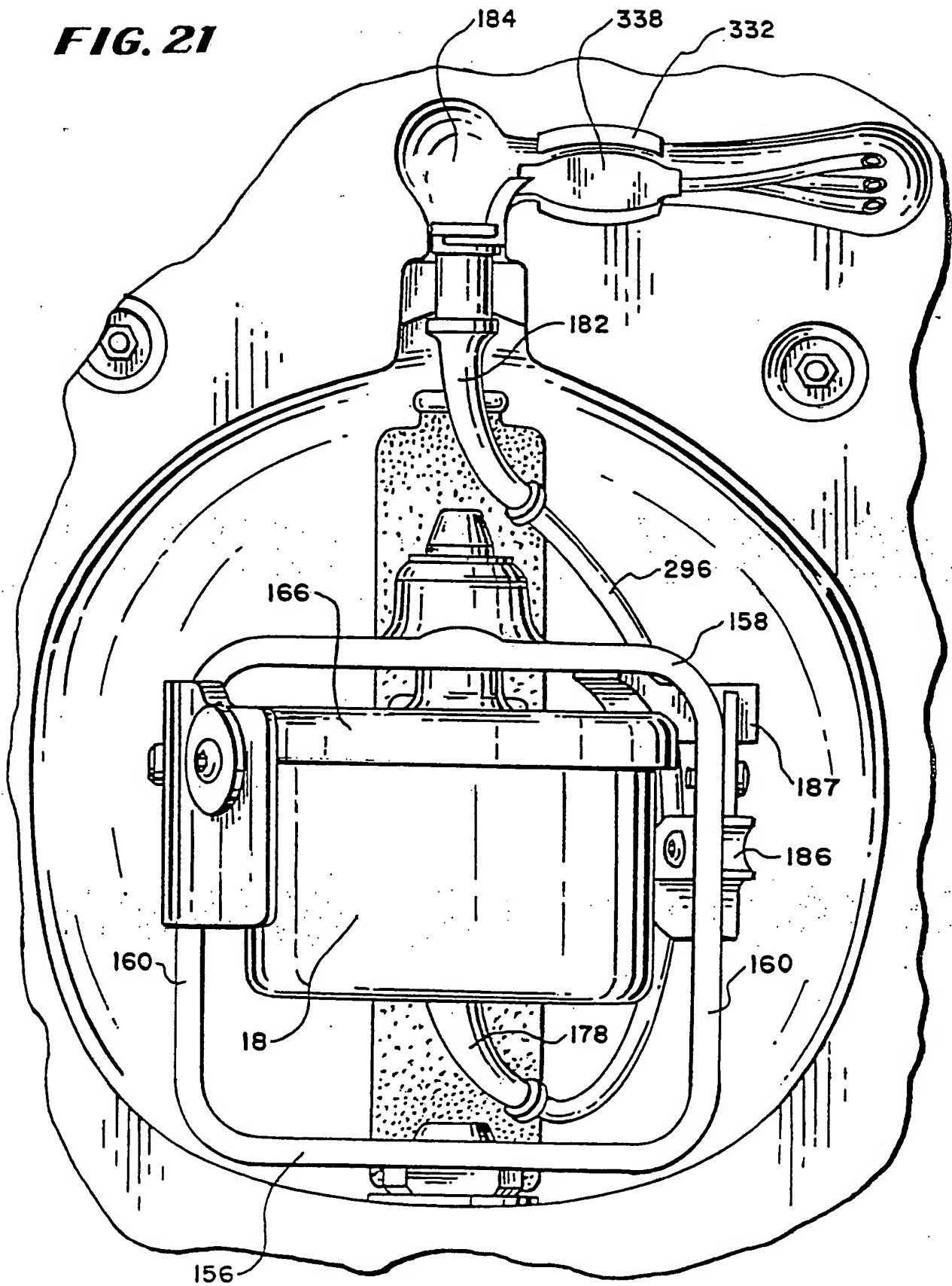
**FIG. 18**



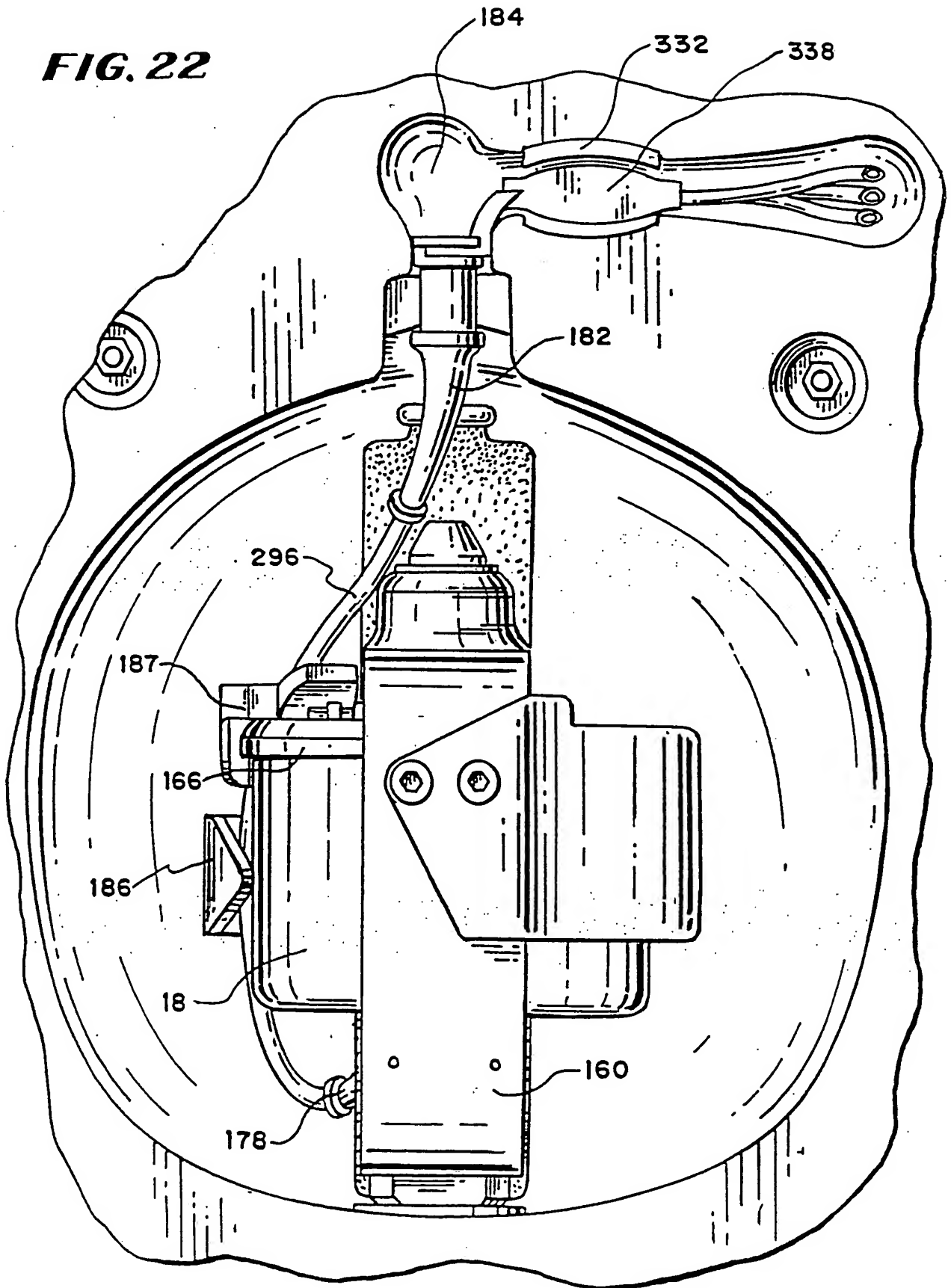
**FIG. 19**

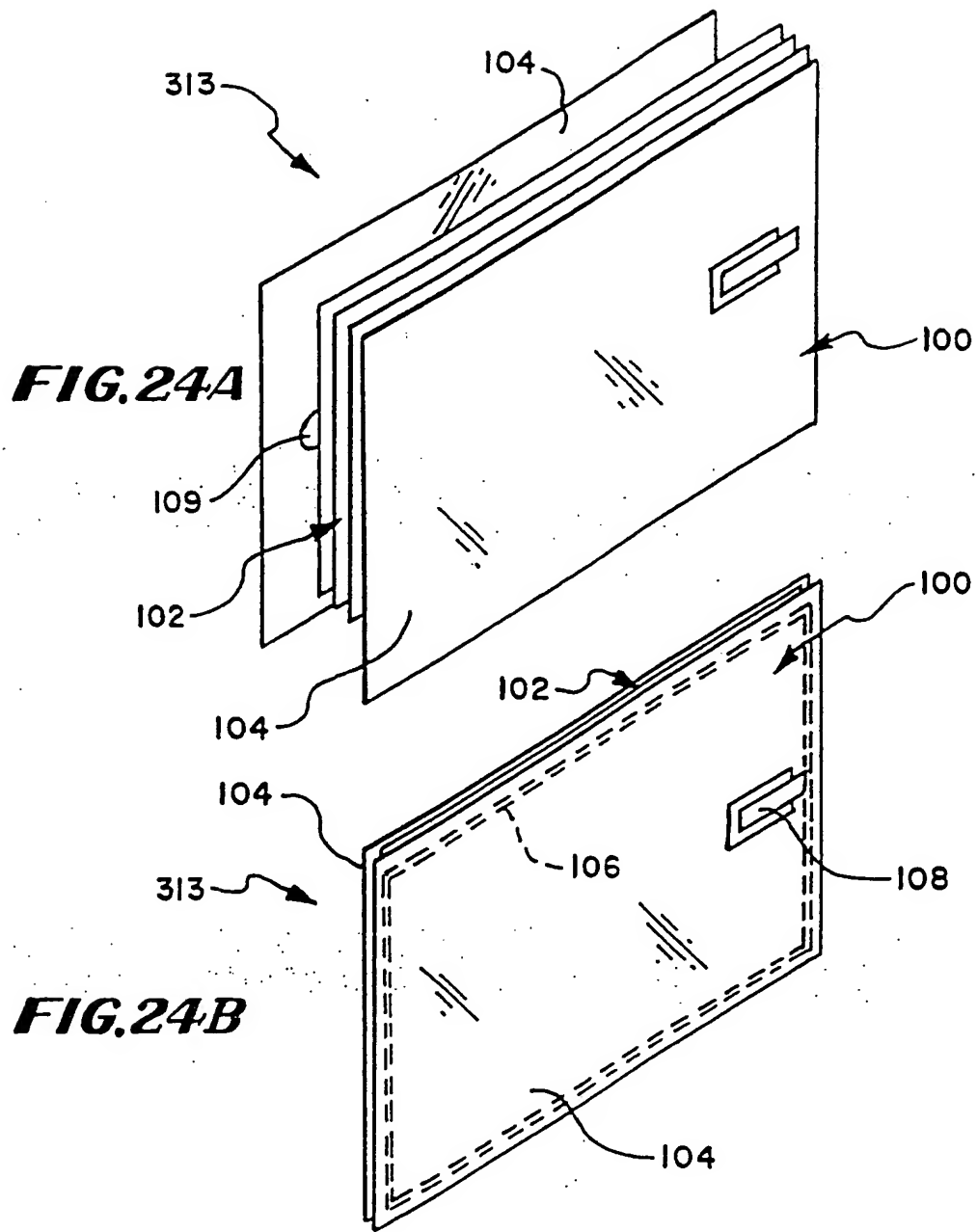
**FIG. 20**

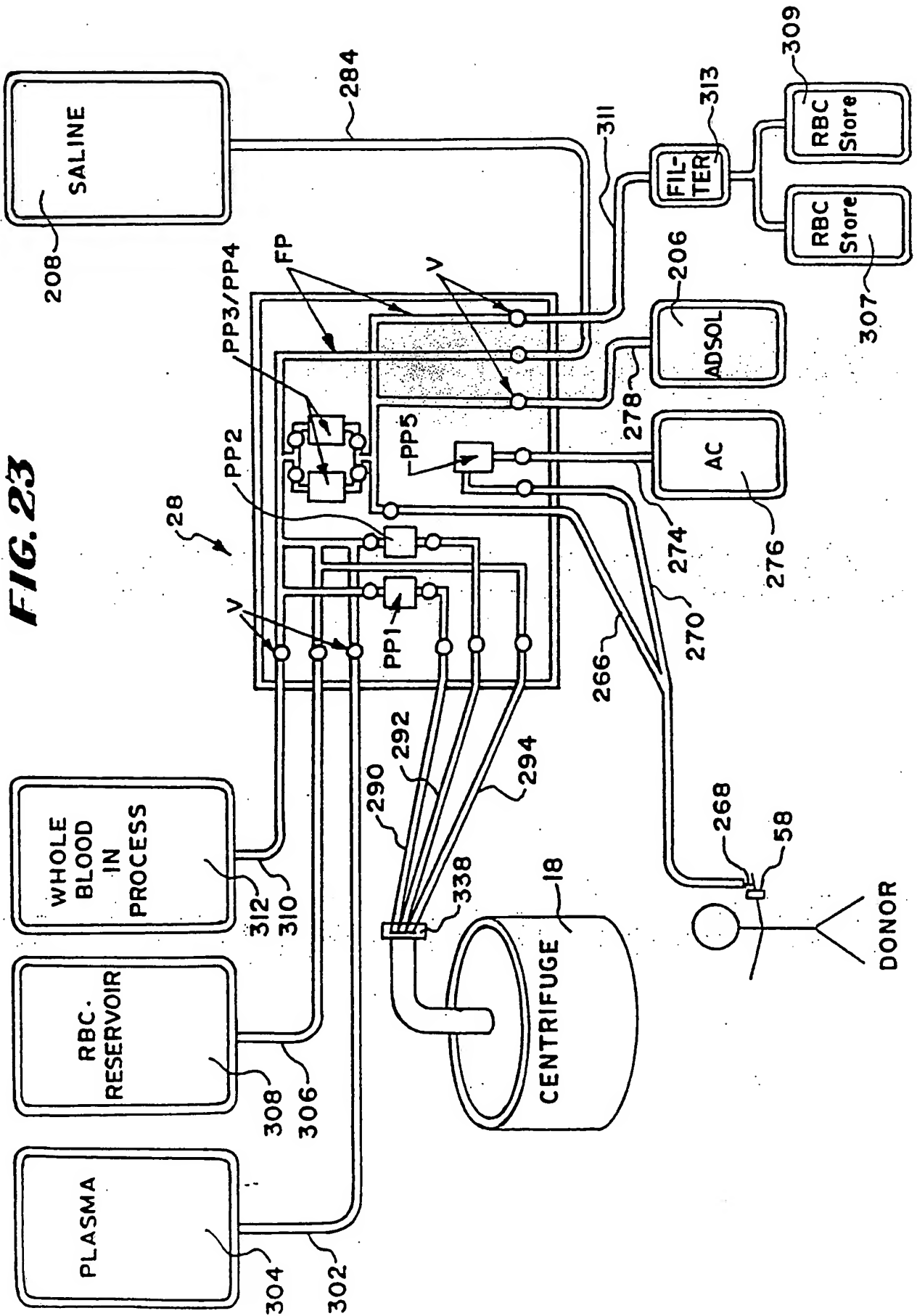


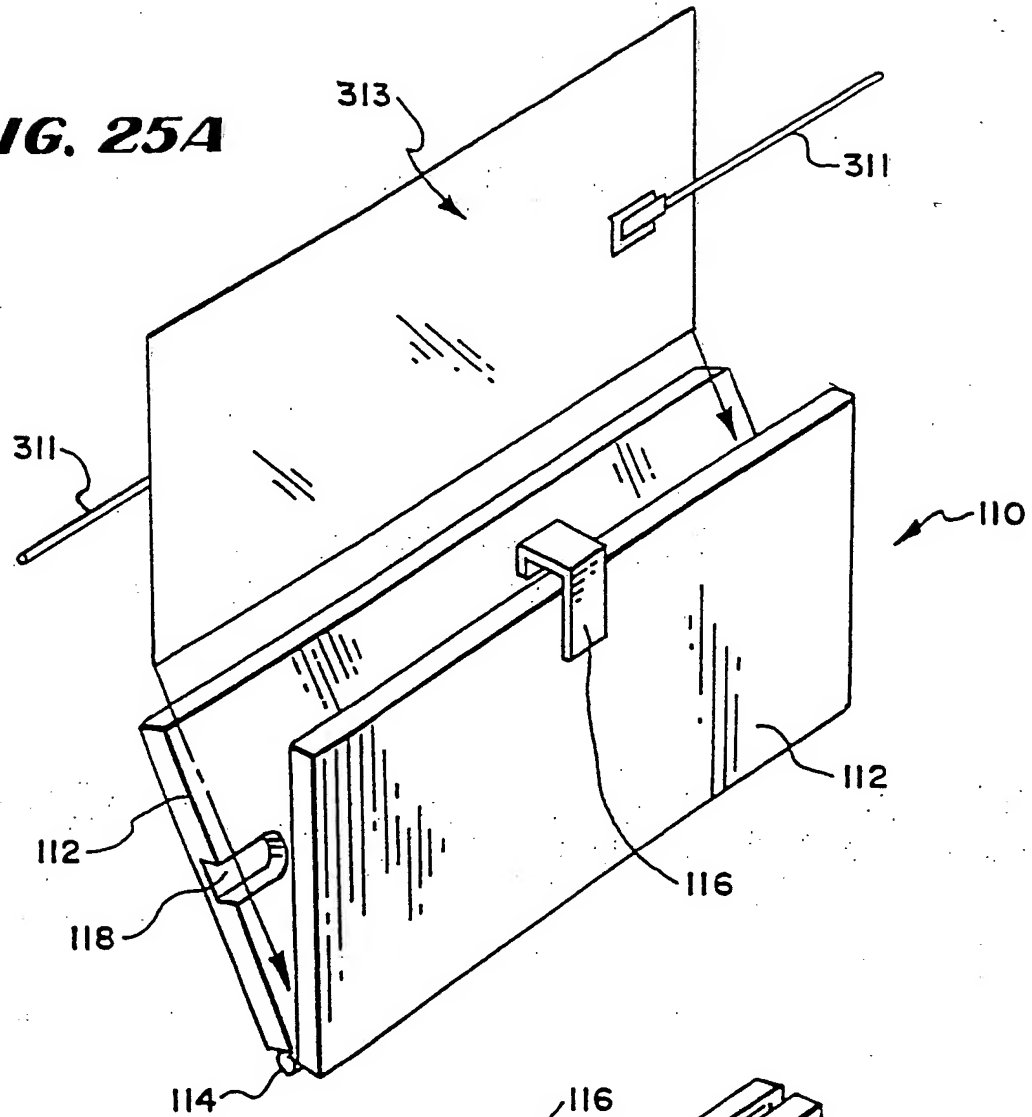
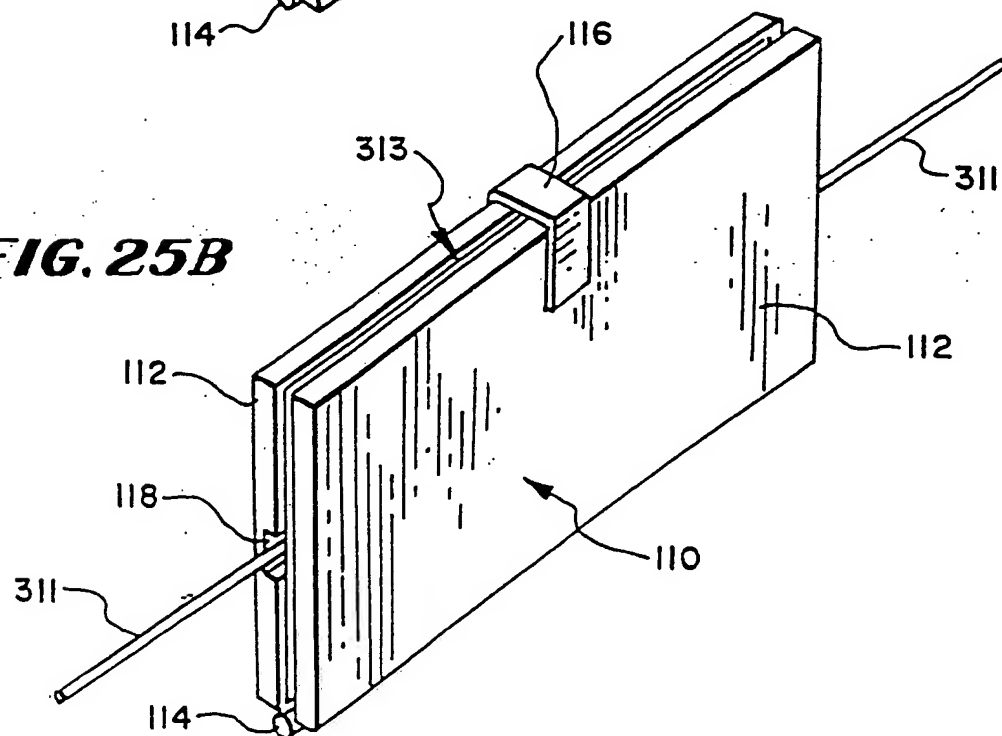
**FIG. 21**

**FIG. 22**



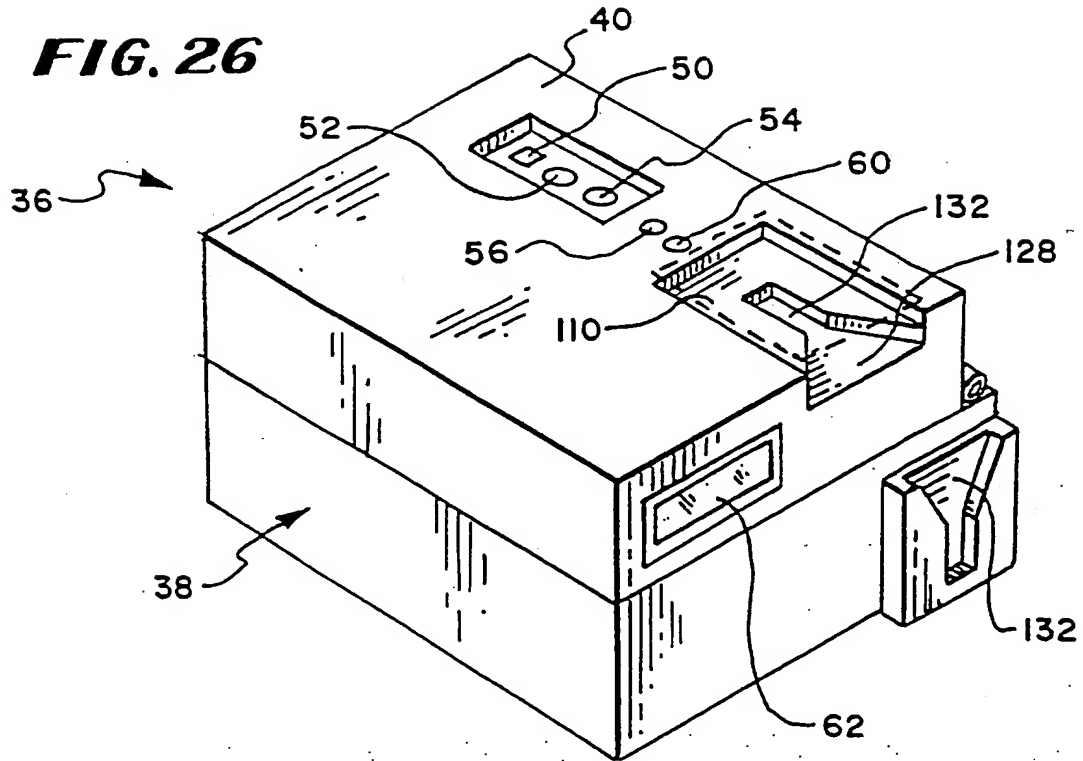


**FIG. 23**

**FIG. 25A****FIG. 25B**

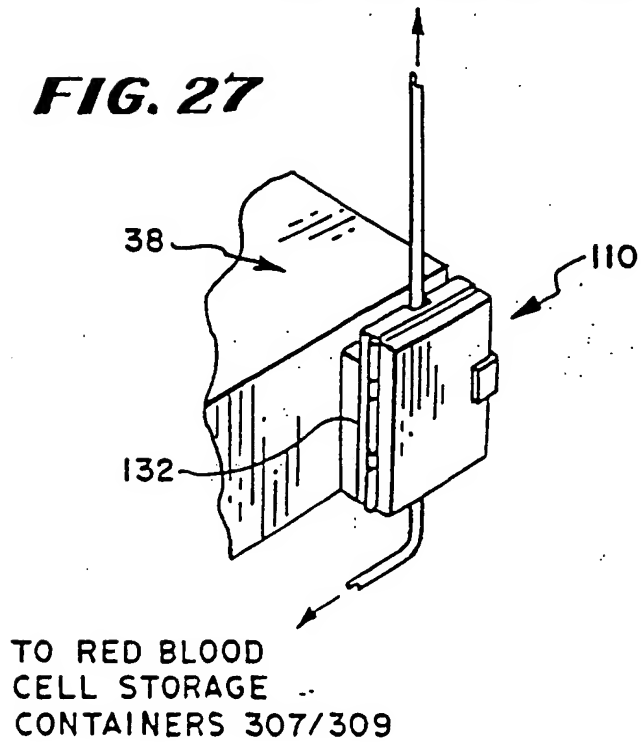
23/24

**FIG. 26**

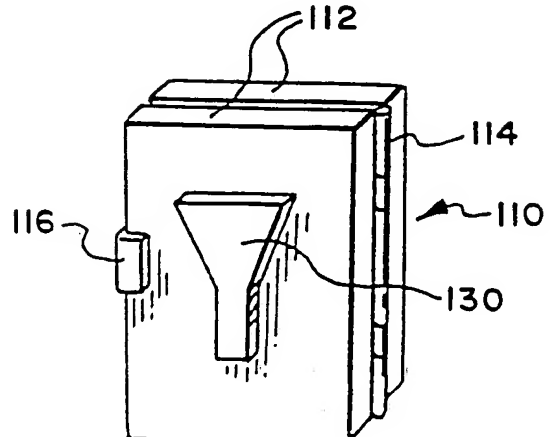


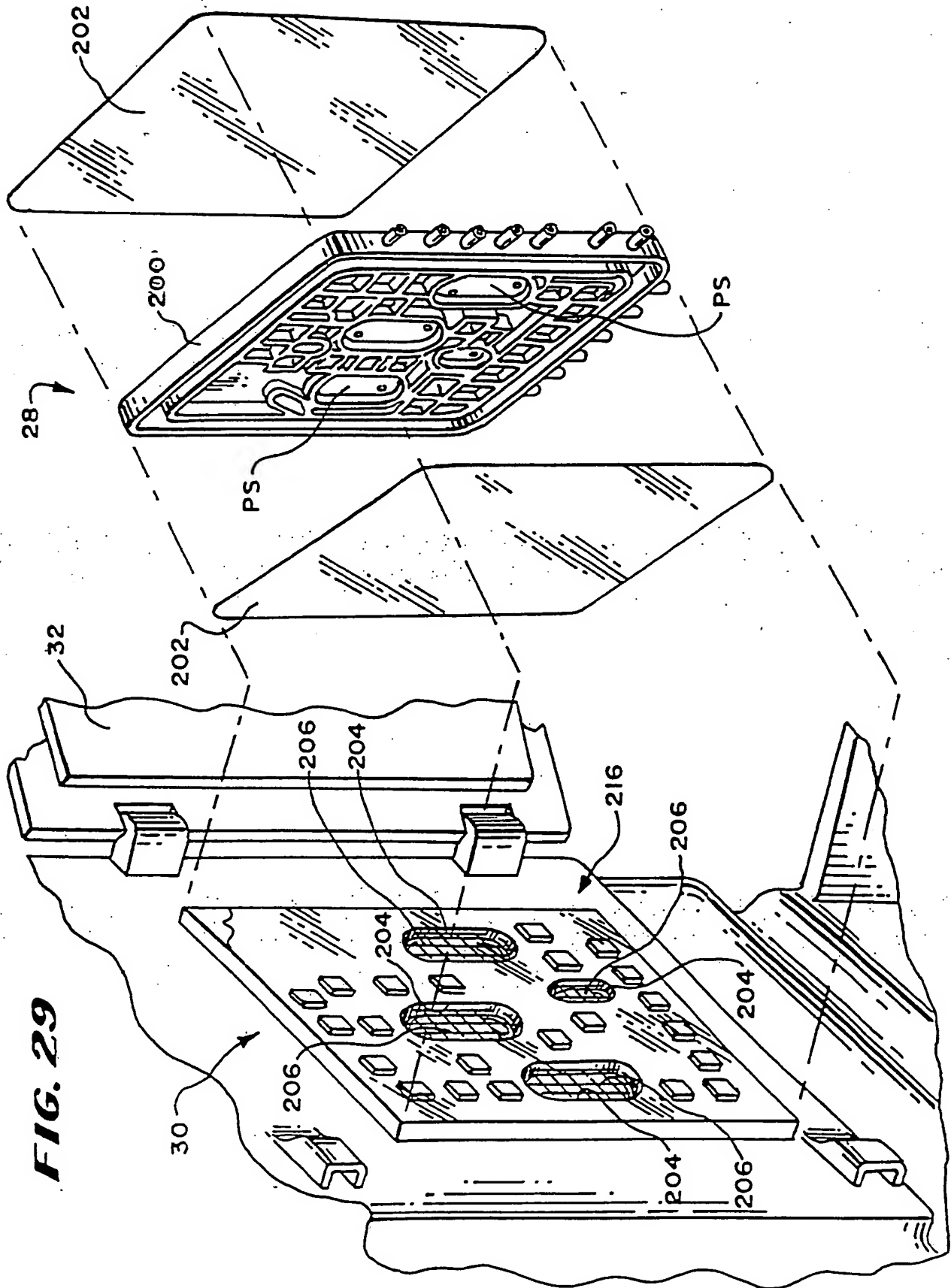
FROM RED BLOOD  
CELL RESERVOIR 308

**FIG. 27**



**FIG. 28**





Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Please amend the application prior to the first office action as follows:



### AMENDMENT TO THE CLAIMS

1 (Original). A blood processing system comprising

a blood processing set including a source of blood cells, and a blood component collection flow channel coupled to the source of blood cells including a blood cell storage container and an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container, the in-line filter including a fibrous filter medium, first and second flexible housings, a unitary, continuous peripheral seal formed by application of pressure and radio-frequency heating in a single process to join the first and second flexible housings to each other, as well as join the fibrous filtration medium to the first and second flexible housings, and

a pump station adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter.

2 (Original). A blood processing system according to claim 1

further including a fixture to restrain expansion of the first and second filter housings as a result of pressure applied during operation of the pump station.

3 (Original). A blood processing system according to claim 2

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

4 (Original). A blood processing system according to claim 1

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

5 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the controller includes a function to derive a value reflecting volume of blood cells present in the blood cell storage container after passage through the filter as a percentage of volume of blood cells conveyed to the filter.

6 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the pump station includes a fluid pressure actuated pump and an actuator to apply fluid pressure to the pump.

7 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the blood cells comprise red blood cells.

8 (Original). A method of processing blood comprising using the blood processing system as defined in claim 1 or 2 or 3 or 4.

9 (New). In a method of filtering a liquid using a filter comprising a flexible housing having an inlet port and outlet port for the liquid and a sheet-like filter element for removing undesired components from the liquid, with the inlet port being separated from the outlet port by the filter element, a method characterized by maintaining the pressure at the outlet side of the filter at a positive pressure above atmospheric pressure by controlling a feed rate per unit time of a feed pump installed in an upstream flow channel of the filter.

10 (New). The method according to claim 9, wherein the filter does not comprise a spacer for securing a flow channel at the outlet side of the filter.

11 (New). The method according to claim 9 or claim 10, wherein the filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet side and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

12 (New). The method according to claim 9, wherein the liquid to be filtered is blood.

13 (New). The method according to claim 10, wherein the liquid to be filtered is blood.

14 (New). The method according to claim 11, wherein the liquid to be filtered is blood.

15 (New). The method according to claim 12, wherein the filter is used for removal of leukocytes.

16 (New). The method according to claim 13, wherein the filter is used for removal of leukocytes.

17 (New). The method according to claim 14, wherein the filter is used for removal of leukocytes.

18 (New). In a filtering system for a liquid comprising a filter comprising a flexible housing having an inlet port and outlet port for the liquid, a sheet-like filter element for removing undesired components from the liquid, with the liquid inlet port and the outlet port separated from each other by the filter element, an upstream side flow channel connected to the filter inlet port, a filtered liquid recovery bag, a downstream side flow channel connecting the filter outlet port with the recovery bag, and a feed pump installed in the upstream side flow channel, a filtering system wherein the feed

rate per unit time of a feed pump installed in an upstream flow channel of the filter can be controlled so that the pressure at the outlet side of the filter is maintained at positive pressure above atmospheric pressure.

19 (New). The system according to claim 18, comprising the filter without a spacer for securing a flow channel at the outlet side of the filter.

20 (New). The system according to a claim 18 or claim 19, wherein a filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet port and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

21 (New). The system according to claim 18, wherein the liquid to be filtered is blood.

22 (New). The system according to claim 19, wherein the liquid to be filtered is blood.

23 (New). The system according to claim 20, wherein the liquid to be filtered is blood.

24 (New). The system according to claim 21, wherein the filter is used for removal of leukocytes.

25 (New). The system according to claim 22, wherein the filter is used for removal of leukocytes.

26 (New). The system according to claim 23, wherein the filter is used for removal of leukocytes.

27 (New). A liquid filtering method using the system according to claim 18.

28 (New). A liquid filtering method using the system according to claim 19.

29 (New). A liquid filtering method using the system according to claim 20.

30 (New). A liquid filtering method using the system according to claim 21.

31 (New). A liquid filtering method using the system according to claim 22.

32 (New). A liquid filtering method using the system according to claim 23.

33 (New). A liquid filtering method using the system according to claim 24.

34 (New). A liquid filtering method using the system according to claim 25.

35 (New). A liquid filtering method using the system according to claim 26.

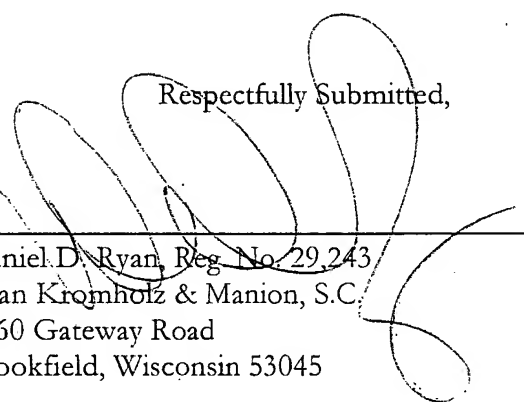
### REMARKS

New claims 9 to 35 have been added. The new claims are patterned after claims 11 to 16 and 29 to 35 of co-pending United States Patent Application Serial No. 10/474,805, filed April 2, 2002 (Foreign Priority: April 13, 2001), entitled "Liquid Filtering Method and Filtering System." With respect to these new claims 9 to 35, applicant concurrently files a document Suggesting an Interference Pursuant to 37 C.F.R. § 41.202(a), with companion Declarations.

Applicant notes that the instant application is a continuation of United States Patent Application Serial No. 09/976,833, filed October 13, 2001, now United States Patent No. 6,709,412.

A request for Correction of Inventorship also accompanies this Amendment, by the addition of co-inventors and Tom Westberg and Rohit Vishnoi. The submission of new claims 9 to 35 necessitated this request. The co-inventors of the subject matter defined in new claims 9 to 35 are Mark Vandlik, Tom Westberg, and Rohit Vishnoi.

Respectfully Submitted,

By   
Daniel D. Ryan, Reg. No. 29,243  
Ryan Kromholz & Manion, S.C.  
3360 Gateway Road  
Brookfield, Wisconsin 53045

Gary W. McFarron, Reg. No. 27,357  
David Lesht, Reg. No. 30,472  
Cook, Alex, McFarron, Manzo, Cummings & Mehler  
200 W. Adams St., Suite 2850  
Chicago, Illinois 60606

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308

Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**Request for Correction of Inventorship**

**Pursuant to 37 C.F.R. §1.48(c)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant hereby requests, pursuant to 37 C.F.R. §1.48(c), correction of inventorship in the above identified case by the addition of joint inventors Tom Westberg and Rohit Vishnoi. The addition of inventors is necessitated by amendment of the claims to add subject matter not present in the claims at the time this case was filed.

As required by 37 C.F.R. §1.48(b), accompanying this Request are:

1. Statements from added inventors Tom Westberg and Rohit Vishnoi that their addition is necessitated by amendment of the claims and that the inventorship error occurred without any deceptive intent on his part (TAB 1).
2. An assignment, executed by the added inventors Tom Westberg and Rohit Vishnoi, with a Request for Recordation (TAB 2). The assignment of the originally inventors Mark R. Vandlik, Michael J. Kast, and Kelly B. Smith has been previously recorded in the parent application (Serial Number 09/976833, now US 6,709,412) in Reel/Frame 012582/0905.
3. The written consent of the assignee to the correction (TAB 3).
4. A Declaration by the actual inventors as required by 37 C.F.R. §1.63 (TAB 4). Originally-named inventor (and assignor) Kelly B. Smith cannot at the present time be reached for signature (she has moved and her exact whereabouts are not known), and a Petition under 37 C.F.R. § 1.183

(TAB 5) requesting a waiver of the requirement of 37 C.F.R. § 1.64 when as here, assignee has consented to the correction (see MPEP 201.03 (B)), accompanies this Petition for Correction.

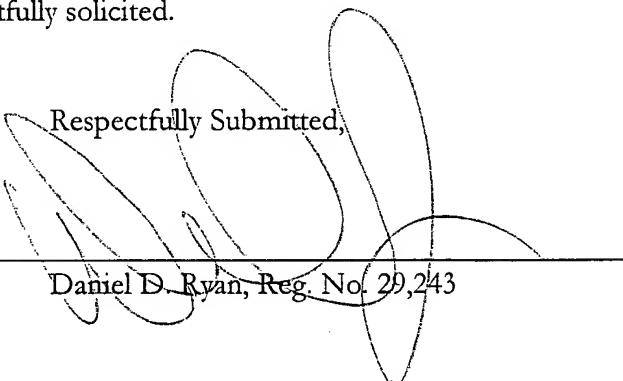
5. The processing fee as set forth in 37 C.F.R. §1.17(i).

A check payable in an amount to cover the requisite processing fee for this Request to Change Inventorship and Request for Recordation of Assignment is attached. You are authorized to charge any excess fees, or to credit overpayments, to Deposit Account No. 06-2360. A copy of this Request (without attachments) is attached for this purpose.

Approval of this Request is respectfully solicited.

Respectfully Submitted,

By

  
Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308

Customer No.: 26308

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

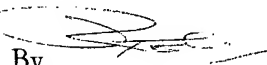
Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**STATEMENT OF ROHIT VISHNOI  
UNDER 37 C.F.R. 1.48(c) (2)**

I, Rohit Vishnoi, do understand that a petition has been made to change the inventorship in this patent by adding me as a joint inventor. I also understand that the addition was necessitated by amendment of the claims. The inventorship error occurred without any deceptive intention on my part.

I know that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the patent issued hereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Dated 7/28/05

By   
Rohit Vishnoi

Customer No.: 26308

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

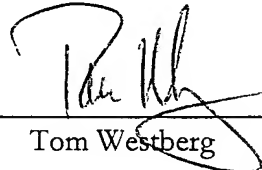
Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**STATEMENT OF TOM WESTBERG  
UNDER 37 C.F.R. 1.48(c) (2)**

I, Tom Westberg, do understand that a petition has been made to change the inventorship in this patent by adding me as a joint inventor. I also understand that the addition was necessitated by amendment of the claims. The inventorship error occurred without any deceptive intention on my part.

I know that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the patent issued hereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Dated 7/25/05

By   
Tom Westberg



RYAN KROMHOLZ & MANION, S.C.

17287

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DATE	DESCRIPTION	INVOICE #	AMOUNT	DEDUCTION	NET AMOUNT
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RYAN KROMHOLZ & MANION, S.C.

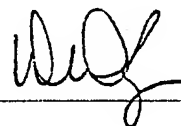
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## RECORDATION FORM COVER SHEET PATENTS ONLY

To the Director of the U.S. Patent and Trademark Office: Please record the attached documents or the new address(es) below.

### 1. Name of conveying party(ies)/Execution Date(s):

Tom Westberg  
Rohit Vishnoi

Execution Date(s) 7/25/2005 and 7/28/2005

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

### 3. Nature of conveyance:

- ☒ Assignment ☐ Merger  
☐ Security Agreement ☐ Change of Name  
☐ Government Interest Assignment  
☐ Executive Order 9424, Confirmatory License  
☐ Other \_\_\_\_\_

### 2. Name and address of receiving party(ies)

Name: Baxter International Inc.

Internal Address: \_\_\_\_\_

Street Address: One Baxter Parkway

City: Deerfield

State: Illinois

Country: US Zip: 60015

Additional name(s) & address(es) attached? ☐ Yes ☒ No

### 4. Application or patent number(s):

☐ This document is being filed together with a new application.  
A. Patent Application No.(s)  
10/765,498  
B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

### 5. Name and address to whom correspondence concerning document should be mailed:

Name: Daniel D. Ryan

Internal Address: Ryan Kromholz & Manion, S.C.

Street Address: P.O. Box 26618

City: Milwaukee

State: Wisconsin Zip: 53226

Phone Number: 262 783 1300

Fax Number: 262 783 1211

Email Address: \_\_\_\_\_

### 6. Total number of applications and patents involved:

7. Total fee (37 CFR 1.21(h) & 3.41) \$ 40.00

- ☐ Authorized to be charged by credit card  
☐ Authorized to be charged to deposit account  
☒ Enclosed  
☐ None required (government interest not affecting title)

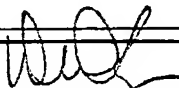
### 8. Payment Information

a. Credit Card Last 4 Numbers \_\_\_\_\_  
Expiration Date \_\_\_\_\_

b. Deposit Account Number 06-2360

Authorized User Name Daniel D. Ryan

### 9. Signature:



Signature

4 August 2005

Date

Daniel D. Ryan

Name of Person Signing

Total number of pages including cover sheet, attachments, and documents:

Serial No. (1) 10/765,498Filed (1) 01/26/2004

In consideration of ONE DOLLAR and other good and valuable considerations, the receipt and sufficiency whereof are hereby acknowledged, we hereby assign to BAXTER INTERNATIONAL INC. (hereinafter referred to as "assignee"), a corporation of Delaware, having a principal place of business at DEERFIELD, ILLINOIS, its successors, legal representatives and assigns, the entire right, title and interest throughout the world in our invention or improvements in

(2) **Blood Processing Systems and Methods that Employ an  
In-Line Leukofilter Mounted in a Restraining Fixture**

and in the application for Letters Patent of the United States therefor, executed by each of us individually on the date(s) indicated below and any and all other United States applications and applications in any and all countries which we may file, either solely or jointly with others, on said invention or improvements, and in any and all Letters Patent of the United States or of any other country which may be obtained on any of the said applications, and in any reissue or extension thereof.

We hereby authorize and request the Commissioner of Patents to issue said Letters Patent to said BAXTER INTERNATIONAL INC.

We hereby authorize and request the attorneys of record in said application to insert in this assignment the date and serial number of said application when officially known.

We warrant ourselves to be the owners of the interest herein assigned and to have the right to make this assignment; and further warrant that there are no outstanding prior assignments, licenses, or other rights in the interest herein assigned.

For said considerations we hereby agree, upon the request and at the expense of said assignee, its successors, legal representatives and assigns, to execute any and all divisional, continuation, and renewal applications for said invention or improvements, and any necessary oath or supplemental oath or affidavit relating thereto, and any application for the reissue or extension of any Letters Patent that may be granted upon said application that said assignee, its successors, legal representatives and assigns may deem necessary or expedient, and for the said considerations we further agree, upon the request of said assignee, its successors, legal representatives and assigns, in the event of said application or any division thereof, or Letters Patent issued thereon, or any reissue or application for the reissue thereof becoming involved in interference, to cooperate to the best of our ability with said assignee, its successors, legal representatives and assigns in the matters of preparing and executing the preliminary statement and giving and producing evidence in support thereof. We further agree to perform, upon such request, any and all affirmative acts to obtain Letters Patent, and vest all rights therein hereby conveyed in the said assignee, its successors, legal representatives and assigns whereby said Letters Patent will be held and enjoyed by the said assignee, its successors, legal representatives and assigns to the end of the term for which said Letters Patent may be granted as fully and entirely as the same would have been held and enjoyed by us if this assignment and sale had not been made, and for the said considerations we hereby also assign to said assignee, its successors, legal representatives and assigns the entire right, title and interest in said invention or improvements for any and all foreign countries and the right of priority for patent and utility model applications in all countries arising under any applicable international convention for the protection of industrial property and/or any internal priority legislation of such countries, and we further agree upon the request of said assignee, its successors, legal representatives and assigns to execute any and all documents that shall be required to be executed in connection with any and all applications for foreign Letters Patent therefor, including the prosecution thereof, and to execute any and all documents necessary to invest title in said foreign applications and patents in said assignee.

WITNESS our hand and seal

Date 7/25/05 Signature [Signature]  
(3) Typed Name: Tom Westberg

(4) State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by Tom Westberg  
Inventor

\_\_\_\_\_  
Notary Public

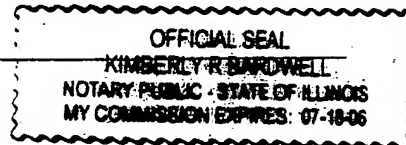
Date 7/28/05 Signature [Signature]  
(3) Typed Name: Rohit Vishnoi

(4) State of Illinois, County of Lake

Signed before me on this 28 day of July, 2005

by Rohit Vishnoi  
Inventor

[Signature]  
Notary Public



Date \_\_\_\_\_ Signature \_\_\_\_\_  
(3) Typed Name: \_\_\_\_\_

(4) State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by \_\_\_\_\_  
Inventor

Date \_\_\_\_\_ Signature \_\_\_\_\_  
(3) Typed Name: \_\_\_\_\_

(4) State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by \_\_\_\_\_  
Inventor



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## Assignments on the Web &gt; Patent Query

## Patent Assignment Abstract of Title

**NOTE: Results display only for issued patents and published applications.  
For pending or abandoned applications please consult USPTO staff.**

## Total Assignments: 1

Patent #: 6709412

Issue Dt: 03/23/2004 Application #: 09976833 Filing Dt: 10/13/2001

Publication #: US20020090319 Pub Dt: 07/11/2002

Inventors: Mark R. Vandlik, Michael J. Kast, Kelly B. Smith

Title: BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN IN-LINE LEUKOFILTER  
MOUNTED IN A RESTRAINING FIXTURE

## Assignment: 1

Reel/Frame: 012582/0905

Recorded: 02/12/2002

Pages: 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: VANDLIK, MARK R.

Exec Dt: 01/22/2002

KAST, MICHAEL J.

Exec Dt: 01/21/2002

SMITH, KELLY B.

Exec Dt: 01/21/2002

Assignee: BAXTER INTERNATIONAL INCONE BAXTER PARKWAY(2-2E)  
DEERFIELD, ILLINOIS 60015

Correspondent: RYAN KROMHOLZ &amp; MANION, S.C.

DANIEL D. RYAN

P.O. BOX 26618

MILWAUKEE, WI 53226

Search Results as of: 08/02/2005 11:11 AM

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Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

CONSENT OF ASSIGNEE  
TO CHANGE OF INVENTORSHIP  
PURSUANT TO 37 C.F.R. §1.48(c)

Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015, the owner of 100% interest in this U.S. Patent Application by virtue of assignment, hereby assents to the correction of inventorship filed herewith, namely adding Tom Westberg and Rohit Vishnoi as co-inventors.

I state that I am authorized to act on behalf of the assignee.

In accordance with 37 C.F.R. 3.73, the assignee hereby certifies that the evidentiary documents with respect to ownership have been reviewed and that, to the best of the assignee's knowledge and belief, title is in the assignee seeking to take this action.

Dated

August 3, 2005

By

David P. Scharf

D.P.S.

Typed Name David P. Scharf

Assistant Corporate Secretary  
Title and Associate General Counsel

**COMBINED DECLARATION AND POWER OF ATTORNEY  
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION OR CIP)**

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type: *(check one applicable item below)*

- ☒ original  
☐ supplemental

Type of Application: *(check one applicable item below)*

- ☐ original  
☐ design

NOTE: *If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.*

- ☐ national stage of PCT

NOTE: *If one of the following items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.*

- ☐ divisional  
☒ continuation  
☐ continuation-in-part (CIP)

**INVENTORSHIP IDENTIFICATION**

WARNING: *If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN  
IN-LINE LEUKOFILTER MOUNTED IN A RESTRAINING FIXTURE

**SPECIFICATION IDENTIFICATION**

the specification of which: *(complete (a), (b) or (c))*

- (a) ☐ is attached hereto.  
(b) ☒ was filed on 26 January 2004 as ☐ Serial No. 10/765,498  
or ☐ Express Mail No., as Serial No. not yet known \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: *Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.*

- (c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
filed on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_  
(if any).

# ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

- [ ] In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

## PRIORITY CLAIM (35 U.S.C. § 119)

- A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

- (d) [ x ] no such applications have been filed.  
(e) [ ] such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]
			[ ] YES NO [ ]

- B. CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application No.	Filing Date
_____	_____
_____	_____
_____	_____

## CLAIM FOR BENEFIT OF EARLIER US and/or PCT APPLICATION(S) UNDER 35 U.S.C. § 120

- [ ] The claim for the benefit of any such applications are set forth in the attached ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR US PRIORITY CLAIM

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

---

---

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. S 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(List name and registration number)*

Daniel D. Ryan (29,243)  
John M. Manion (38,957)  
Laura A. Dable (46,436)  
Patricia A. Limbach (50,295)  
Thomas J. Krumenacher (56,736)

Bradford R.L. Price (29,101)  
Joseph A. Kromholz (34,204)  
Daniel R. Johnson (46,204)  
Patrick J. Fleis (55,185)  
Melissa S. Hockersmith (56,960)

*(check the following item, if applicable)*

- [ ] Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

---

SEND CORRESPONDENCE TO

Bradford R.L. Price, Esquire  
BAXTER HEALTHCARE CORPORATION  
Senior Counsel  
One Baxter Parkway (DF3-2E)  
Deerfield, IL 60015

DIRECT TELEPHONE CALLS TO:  
(Name and telephone number)

Bradford R.L. Price  
(847) 948-4483

---

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

MARK (GIVEN NAME) R (MIDDLE INITIAL OR NAME) VANDLIK (FAMILY (OR LAST NAME))  
 Inventor's signature *Mark Vandlik*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS HAWTHORN WOODS, IL  
 Post Office Address 7742 GENEVA DRIVE #7 OLD LAKE ROAD  
GURNEE, ILLINOIS 60031 HAWTHORN WOODS, IL 60047 *7/27/05*

Full name of second joint inventor, if any

MICHAEL (GIVEN NAME) J (MIDDLE INITIAL OR NAME) KAST (FAMILY (OR LAST NAME))  
 Inventor's signature *Michael J Kast*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) EVANSTON, ILLINOIS  
 Post Office Address 1152 ASHLAND AVENUE  
EVANSTON, ILLINOIS 60202

Full name of third joint inventor, if any

KELLY (GIVEN NAME) B (MIDDLE INITIAL OR NAME) SMITH (FAMILY (OR LAST NAME))  
 Inventor's signature \_\_\_\_\_  
 Date \_\_\_\_\_ Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 506 CRYSTAL PLACE  
GURNEE, ILLINOIS 60031

Full name of fourth joint inventor, if any

TOM (GIVEN NAME) (MIDDLE INITIAL OR NAME) WESTBERG (FAMILY (OR LAST NAME))  
 Inventor's signature *Tom Westberg*  
 Date 7/25/2005 Country of Citizenship FI  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 17820 POND RIDGE CIRCLE  
GURNEE, ILLINOIS 60031

Full name of fifth joint inventor, if any

ROHIT (GIVEN NAME) (MIDDLE INITIAL OR NAME) VISHNOI (FAMILY (OR LAST NAME))  
 Inventor's signature *Rohit Vishnoi*  
 Date 7/25/2005 Country of Citizenship US  
 Residence (City, State/Country) DEERFIELD, ILLINOIS  
 Post Office Address 235 WILSON AVENUE  
DEERFIELD, ILLINOIS 60015

**ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR US PRIORITY CLAIM****CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120**

I hereby claim the benefit under Title 35, United States Code, S 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, S 112, I acknowledge the duty to disclose information that is material to the examination of this application, namely, information where there is substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:**Status  
(CHECK ONE)

U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Abandoned
1. 09/976,833	10/13/2001	X		
2. 09/389,504	09/03/1999			X
3. _____	_____	_____	_____	_____

**PCT APPLICATIONS DESIGNATING THE U.S.**

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NOS. ASSIGNED (if any)
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

**35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS****DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY APPLICATION  
CLAIMED UNDER 35 USC 119**

	Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

CHECK PROPER BOX 3) FOR ANY OF THE FOLLOWING ADD PAGE(S) WHICH  
FORM A PART OF THIS DECLARATION

- ☐ Signature for sixth and subsequent joint inventors.

\* \* \*

- ☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor.

\* \* \*

- ☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47.

\* \* \*

- ☒ Added page to combined declaration and power of attorney for US Priority Claim

\* \* \*

- ☐ Authorization of attorney(s) to accept and follow instructions from representative

\* \* \*

*(If no further pages form a part of this declaration then end this declaration with this page and check the following item:)*

- ☐ This declaration ends with this page

RYAN KROMHOLZ & MANION, S.C.

17289

		CHECK			
DATE	DESCRIPTION	INVOICE #	AMOUNT	DEDUCTION	NET AMOUNT
08/04/05	Commissioner for Patents F-5489 CIP 2 CON Petition 37 CFR 1.183		130.00		130.00

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08/04/05	17289		130.00	0.00	130.00

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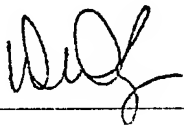
RYAN KROMHOLZ & MANION, S.C.  
POST OFFICE BOX 26618  
MILWAUKEE, WI 53226-0618

ASSOCIATED BANK  
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08/04/05	****	\$130.00

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Details on back.  
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Customer No.: 26308

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**Petition Pursuant to 37 C.F.R. §1.183**

**Requesting Waiver of Requirement of 37 C.F.R. § 1.64**

**That an Original Inventor (Kelly B. Smith) Execute New Oath or Declaration**

**When New Inventors Are Added With Assignee's Consent**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant has requested, pursuant to 37 C.F.R. §1.48(c), a correction of inventorship in the above identified case by the addition of joint inventors Tom Westberg and Rohit Vishnoi. The addition of inventors is necessitated by amendment of the claims to add subject matter not present in the claims at the time this case was filed. Statements under 37 C.F.R. §1.48(c)(2); assignments; and a new Declaration have been executed by added inventors Tom Westberg and Rohit Vishnoi and have been submitted with the request. Original inventors Mark R. Vandlik and Michael Kast have also executed the new Declaration. However, original inventor Kelly B. Smith has not, as yet, been located to obtain her signature on the new Declaration. Active efforts are ongoing to locate her and ask her to join in on the execution of the new Declaration.

An assignment, executed by the original inventors Mark Vandlik, Michael Kast, and Kelly B. Smith has been previously recorded in the parent application (Serial Number 09/976833, now US 6,709,412) in Reel/Frame 012582/0905. The assignee Baxter International Inc. has consented to the correction of inventorship.

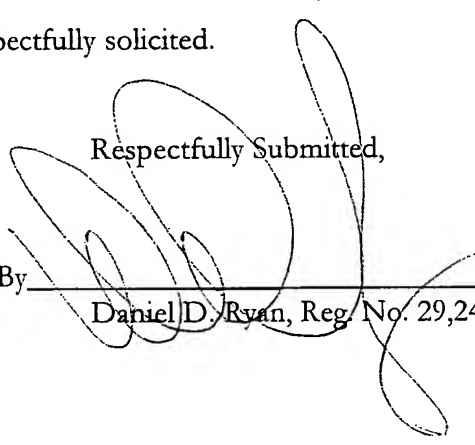
Under such circumstances, as directed by MPEP 201.03 (B), applicant submits this Petition under 37 C.F.R. § 1.183, requesting a waiver of the requirement of 37 C.F.R. § 1.64 that Kelly B. Smith sign the new Declaration, when as here, the assignee has consented to the correction to add new inventors.

The processing fee as set forth in 37 C.F.R. §1.17(i) accompanies this Petition. You are authorized to charge any excess fees, or to credit overpayments, to Deposit Account No. 06-2360. A copy of this Petition is attached for this purpose.

Approval of this Petition is respectfully solicited.

Respectfully Submitted,

By

  
Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308

Customer No.: 26308

Patent



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP 2 CON

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: 26 January 2004

Group Art Unit: 3761

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**DECLARATION OF JUDITH M. DUNAWAY**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, JUDITH M. DUNAWAY, being duly warned do hereby declare:

1. I have been employed by the law firm of Ryan Kromholz & Manion, S.C. since 1987 in the capacity of docket supervisor.

2. On 01 June 2006, I was instructed by Daniel D. Ryan to telephone Kelly B. Smith to let her know that documents were being forwarded to her for signature for this application. The phone number provided to me by Daniel D. Ryan was 630-848-0868. Upon calling this number, I found that this number is disconnected and no further information was available. I relayed this information to Daniel D. Ryan

3. Also on 01 June 2006, I was instructed by Daniel D. Ryan to attempt to locate Kelly B. Smith, via internet searches. I was able to locate Kelly Smith in Naperville, Illinois with a phone number of 630-922-7378. Upon calling this number, I found that it was also disconnected and no further information was available. I relayed this information to Daniel D. Ryan.

4. On 2 June 2006 I personally prepared and deposited with the United States Postal Service the documents and correspondences addressed to Kelly B. Smith attached as Exhibit 1. Exhibit 1 contains a copy of the above referenced patent application in its entirety, as well as the necessary signature documents for Kelly B. Smith. These documents were sent to the last known residential address for Kelly B. Smith, 5S486 Arlington Avenue, Naperville, Illinois 60540.

5. Investigator Alan L. Leisten, hired by Ryan Kromholz & Manion to help in locating Kelly B. Smith, was able to determine that she has moved from Naperville, Illinois to Stroudsburg, Pennsylvania. Mr. Leisten provided me with a phone number for "K Smith" in Stroudsburg, Pennsylvania (570-503-5924). On 7 June 2006 and 8 June 2006, I was instructed by Daniel Ryan to call the number in Stroudsburg, Pennsylvania, to find out if this was the current phone number for Kelly B. Smith. I made numerous attempts to contact someone at this phone number. An answering machine with a pre-recorded voice message allowed me to leave a voice mail message explaining my inquiry with a request for a return phone call. No return phone call has been received to date.

6. No information has been received to date from the U.S. Postal Service as to the status of the correspondence mailed to Kelly B Smith on June 2, 2006.

I declare that all statements made herein of my own knowledge are true; all statements made on information and belief are believed to be true; that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC 1001, and that such willful, false statements may jeopardize the validity of the application or of this document or of any patent issuing therefrom.

Dated this 8th day of June, 2006.

By: Judith M. Dunaway  
Judith M. Dunaway



# RYAN KROMHOLZ & MANION, S.C.

ATTORNEYS AT LAW

Daniel D. Ryan  
Joseph A. Kromholz  
John M. Manion  
Laura A. Dable  
Daniel R. Johnson  
Patrick J. Fleis  
Melissa S. Hockersmith  
Thomas J. Krumenacher

Telephone: (262) 783-1300  
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Mailing Address:  
P.O. Box 26618  
Milwaukee, WI 53226-0618

Building Address:  
3360 Gateway Road  
Brookfield, WI 53045

Fond du Lac Office:  
74 S. Main Street, Suite 103  
Fond du Lac, WI 54935

Arnold J. Ericson (Of Counsel)  
Donald Cayen (Of Counsel)

2 June 2006

Kelly B. Smith  
5S486 Arlington Avenue  
Naperville, IL 60540

Re: F-5489 CIP 2 CON (USSN 10/765,498)  
Blood Processing Systems and Methods that Employ an In-Line Leukofilter Mounted in a Restraining Fixture

Dear Kelly:

We are trying to locate you to have you sign the attached Declaration.

This concerns the filing of a continuation patent application of a case on which you were named a joint inventor along with Mark Vandlik and Michael Kast. The case as originally filed (and which has issued as US Patent No. 6,709,412) was directed to the restraining fixture for the flexible leukodepletion filter. The continuation claims are more broadly directed to the concept of using a pump to direct blood through a flexible filter, and for that reason we added two new inventors, Tom Westberg and Rohit Vishnoi. I attach a copy of the application as filed, and documents signed by Tom, Rohit, Mark and Michael, as well as a consent from the assignee, Baxter to the new list of inventors.

At the time we submitted these papers, we did not know your current whereabouts. We since obtained the above address and a telephone number, but when we called the number we were told it was disconnected. We are sending these materials to the address in the hope that you are still living at this location.

Kindly sign the Declaration at the location tagged and please provide your new address (you can hand-write these in). Please initial and date the new address information.

Please call me or my assistant, Judy Dunaway, as soon as you receive these materials so we can arrange a courier to pick them up and return them to us.

Cordially,  
RYAN KROMHOLZ & MANION, S.C.

By:

Daniel D. Ryan

DDR:jd  
Enclosure - As Stated

**COMBINED DECLARATION AND POWER OF ATTORNEY  
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION OR CIP)**

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type: *(check one applicable item below)*

- ☒ original  
☐ supplemental

Type of Application: *(check one applicable item below)*

- ☐ original  
☐ design

NOTE: *If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.*

- ☐ national stage of PCT

NOTE: *If one of the following items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.*

- ☐ divisional  
☒ continuation  
☐ continuation-in-part (CIP)

**INVENTORSHIP IDENTIFICATION**

WARNING: *If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN  
IN-LINE LEUKOFILTER MOUNTED IN A RESTRAINING FIXTURE

**SPECIFICATION IDENTIFICATION**

the specification of which: *(complete (a), (b) or (c))*

- (a) ☐ is attached hereto.  
(b) ☒ was filed on 26 January 2004 as ☐ Serial No. 10/765,498  
or ☐ Express Mail No., as Serial No. not yet known \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: *Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.*

- (c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
filed on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_  
\_\_\_\_\_ (if any).

# ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

- ☐ In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

## PRIORITY CLAIM (35 U.S.C. § 119)

- A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

- (d) ☒ no such applications have been filed.  
(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>

- B. CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application No.	Filing Date
_____	_____
_____	_____
_____	_____

## CLAIM FOR BENEFIT OF EARLIER US and/or PCT APPLICATION(S) UNDER 35 U.S.C. § 120

- ☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR US PRIORITY CLAIM

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

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NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. S 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (List name and registration number)

Daniel D. Ryan (29,243)  
John M. Manion (38,957)  
Laura A. Dable (46,436)  
Patricia A. Limbach (50,295)  
Thomas J. Krumenacher (56,736)

Bradford R.L. Price (29,101)  
Joseph A. Kromholz (34,204)  
Daniel R. Johnson (46,204)  
Patrick J. Fleis (55,185)  
Melissa S. Hockersmith (56,960)

(check the following item, if applicable)

- [ ] Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

---

SEND CORRESPONDENCE TO

Bradford R.L. Price, Esquire  
BAXTER HEALTHCARE CORPORATION  
Senior Counsel  
One Baxter Parkway (DF3-2E)  
Deerfield, IL 60015

DIRECT TELEPHONE CALLS TO:  
(Name and telephone number)

Bradford R.L. Price  
(847) 948-4483

---

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

MARK (GIVEN NAME) R (MIDDLE INITIAL OR NAME) VANDLIK (FAMILY (OR LAST) NAME)  
 Inventor's signature *Mark Vandlik*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS HAWTHORN WOODS, IL  
 Post Office Address 7712 GENEVA DRIVE 47 OLD LAKE ROAD  
GURNEE, ILLINOIS 60031 HAWTHORN WOODS, IL 60047 *7/29/05*

Full name of second joint inventor, if any

MICHAEL (GIVEN NAME) J (MIDDLE INITIAL OR NAME) KAST (FAMILY (OR LAST) NAME)  
 Inventor's signature *Michael J Kast*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) EVANSTON, ILLINOIS  
 Post Office Address 1152 ASHLAND AVENUE  
EVANSTON, ILLINOIS 60202

Full name of third joint inventor, if any

KELLY (GIVEN NAME) B (MIDDLE INITIAL OR NAME) SMITH (FAMILY (OR LAST) NAME)  
 Inventor's signature *Kelly B Smith*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 506 CRYSTAL PLACE  
GURNEE, ILLINOIS 60031

Full name of fourth joint inventor, if any

TOM (GIVEN NAME) (MIDDLE INITIAL OR NAME) WESTBERG (FAMILY (OR LAST) NAME)  
 Inventor's signature *Tom Westberg*  
 Date 7/25/2005 Country of Citizenship FI  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 17820 POND RIDGE CIRCLE  
GURNEE, ILLINOIS 60031

Full name of fifth joint inventor, if any

ROHIT (GIVEN NAME) (MIDDLE INITIAL OR NAME) VISHNOI (FAMILY (OR LAST) NAME)  
 Inventor's signature *Rohit Vishnoi*  
 Date 7/25/2005 Country of Citizenship US  
 Residence (City, State/Country) DEERFIELD, ILLINOIS  
 Post Office Address 235 WILSON AVENUE  
DEERFIELD, ILLINOIS 60015

**ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR US PRIORITY CLAIM**

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120**

I hereby claim the benefit under Title 35, United States Code, S 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, S 112, I acknowledge the duty to disclose information that is material to the examination of this application, namely, information where there is substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:**

Status  
(CHECK ONE)

U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Abandoned
1. 09/976.833	10/13/2001	X		
2. 09/389.504	09/03/1999			X
3. _____	_____			

**PCT APPLICATIONS DESIGNATING THE U.S.**

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NOS. ASSIGNED (if any)
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

**35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS**

**DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY APPLICATION  
CLAIMED UNDER 35 USC 119**

	Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

CHECK PROPER BOX (S) FOR ANY OF THE FOLLOWING ADD. PAGE(S) WHICH  
FORM A PART OF THIS DECLARATION

☐ Signature for sixth and subsequent joint inventors.

\*\*\*

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor.

\*\*\*

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47.

\*\*\*

☒ Added page to combined declaration and power of attorney for US Priority Claim

\*\*\*

☐ Authorization of attorney(s) to accept and follow instructions from representative

\*\*\*

*(If no further pages form a part of this declaration then end this declaration with this page and check the following item:)*

☐ This declaration ends with this page

Patent

**BLOOD PROCESSING SYSTEMS AND METHODS**

**THAT EMPLOY AN IN-LINE, FLEXIBLE LEUKOFILTER**

**Related Applications**

This application is a continuation of co-  
5 pending United States Application Serial No. 09/976,833,  
filed October 13, 2001, and entitled Blood Separation  
Systems and Methods that Employ an In-Line Leukofilter  
Mounted in a Restraining Fixture," which is a  
continuation-in-part of United States Patent Application  
10 Serial Number 09/389,504, filed September 3, 1999, and  
entitled "Blood Separation Systems and Methods Using a  
Multiple Function Pump Station to Perform Different On-  
Line Processing Tasks," which is incorporated herein by  
reference.

15 **Field of the Invention**

This invention relates to systems and methods  
for processing and collecting blood, blood constituents,  
or other suspensions of cellular material.

**Background of the Invention**

20 Today people routinely separate whole blood,  
usually by centrifugation, into its various therapeutic  
components, such as red blood cells, platelets, and  
plasma.

Conventional blood processing methods use  
25 durable centrifuge equipment in association with single



use, sterile processing systems, typically made of plastic. The operator loads the disposable systems upon the centrifuge before processing and removes them afterwards.

5                   Conventional blood centrifuges are of a size that does not permit easy transport between collection sites. Furthermore, loading and unloading operations can sometimes be time consuming and tedious.

10                   In addition, a need exists for further improved systems and methods for collecting blood components in a way that lends itself to use in high volume, on line blood collection environments, where higher yields of critically needed cellular blood components, like plasma, red blood cells, and platelets,  
15                   can be realized in reasonable short processing times.

                  The operational and performance demands upon such fluid processing systems become more complex and sophisticated, even as the demand for smaller and more portable systems intensifies. The need therefore exists  
20                   for automated blood processing controllers that can gather and generate more detailed information and control signals to aid the operator in maximizing processing and separation efficiencies.

#### Summary of the Invention

25                   The invention provides systems and methods for processing blood and blood constituents that lend themselves to portable, flexible processing platforms equipped with straightforward and accurate control functions.

30                   One aspect of the invention provides blood processing systems and methods comprising a blood processing set that includes a source of blood cells and a blood component collection flow channel coupled to the source of blood cells. The blood component collection  
35                   flow channel includes a blood cell storage container and

an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container. The in-line filter including a fibrous filter medium, first and second flexible housings, and a unitary, continuous peripheral seal. The peripheral seal is characterized by being formed by application of pressure and radio-frequency heating in a single process, to join the first and second flexible housings to each other, as well as join the fibrous filtration medium to the first and second flexible housings. The blood processing system further includes a pump station adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter.

In one embodiment, the blood processing system further includes a fixture to restrain expansion of the first and second filter housings as a result of pressure applied during operation of the pump station.

In one embodiment, the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood. Other features and advantages of the inventions are set forth in the following specification and attached drawings.

#### Brief Description of the Drawings

Fig. 1 is a perspective view of a fluid processing system that embodies features of the invention, with the doors to the centrifuge station and pump and valve station being shown open to accommodate mounting of a fluid processing set;

Fig. 2 is a perspective view of the system shown in Fig. 1, with the doors to the centrifuge station and pump and valve station being shown closed as they would be during fluid processing operations;

Fig. 3 is a schematic view of a representative

blood processing circuit formed by the fluid processing set shown in Figs. 1 and 2;

Fig. 4 is a perspective view of a blood processing chamber and associated fluid conveying umbilicus that form a part of the fluid processing set shown in Figs. 1 and 2;

Fig. 5 is an exploded top perspective view of the of a two-part molded centrifugal blood processing container, which can form a part of the fluid processing set used in association with the device shown in Figs. 1 and 2;

Fig. 6 is a bottom perspective view of the molded processing container shown in Fig. 5;

Fig. 7 is a side section view of the molded processing container shown in Fig. 5, after connection of an umbilicus;

Fig. 8 is a side section view of a three-part molded centrifugal blood processing container which can form a part of the fluid processing set used in association with the device shown in Figs. 1 and 2;

Fig. 9 is a top view of the molded processing container shown in Fig. 5, showing certain details of the separation channel;

Fig. 10 is an exploded perspective view of the centrifuge station and associated centrifuge assembly of the device shown in Figs. 1 and 2;

Fig. 11 is an enlarged exploded perspective view of the centrifuge assembly shown in Fig. 10;

Fig. 12 is a perspective view of the centrifuge assembly fully assembled and housed in the centrifuge station of the device shown in Figs. 1 and 2, with the blood processing chamber and associated umbilicus also mounted on the centrifuge assembly for use;

Fig. 13 is a perspective view of the rotor

plate that forms a part of the centrifuge assembly shown in Figs. 10 to 12, showing the latch assembly which releasably secures the processing chamber to the centrifuge assembly, the latch assembly being shown in  
5 its chamber retaining position;

Fig. 14 is a side section view of the rotor plate shown in Fig. 13, showing the components of the latching assembly as positioned when the latch assembly is in its chamber retaining position;

10 Fig. 15 is a side section view of the rotor plate shown in Fig. 13, showing the components of the latching assembly as positioned when the latch assembly is in its chamber releasing position;

15 Figs. 16 to 18 are a series of perspective view of the centrifuge station of the device shown in Figs. 1 and 2, showing the sequence of loading the processing chamber and associated umbilicus on the centrifuge assembly prior to use;

20 Figs. 19 to 22 are a series of perspective view of the centrifuge station of the device shown in Figs. 1 and 2, after loading the processing chamber and associated umbilicus on the centrifuge assembly, showing at ninety degree intervals the travel of the umbilicus to impart rotation to the processing chamber, as driven and  
25 restrained by umbilicus support members carried by the yoke;

Fig. 23 is a schematic view of a fluid processing circuit of the type shown in Fig. 3, showing certain details of the arrangement of pumps that convey  
30 blood and fluid through the circuit;

Figs. 24A and 24B are perspective views of a leukofilter that can form a part of the fluid process circuit shown in Figs. 3 and 23, the leukofilter comprising a filter media enclosed between two flexible  
35 sheets of plastic material, Fig. 24A showing the

leukofilter in an exploded view and Fig. 24B showing the leukofilter in an assembled view;

5 Figs. 25A and 25B are perspective views of the leukofilter shown in Fig. 24B in association with a fixture that retains the leukofilter during use, Fig. 25A showing the leukofilter being inserted into an opened fixture and Fig. 25B showing the leukofilter retained for use within a closed fixture;

10 Fig. 26 is a perspective view of a device of a type of shown in Figs. 1 and 2, with the lid of the device closed to also reveal the location of various components and a leukofilter holder carried on the exterior of the lid;

15 Fig. 27 is a partial perspective view of a side of the base of a device of a type shown in Figs. 1 and 2, showing a holder for supporting the leukofilter retaining fixture shown in Figs. 25A and 25B during fluid processing operations;

20 Fig. 28 is a view of one side of the leukofilter retaining fixture of a type shown in Figs. 25A and 25B, showing a mounting bracket that can be used to secure the leukofilter either to the lid-mounted receptacle shown in Fig. 26 or the base-mounted holder shown in Fig. 27; and

25 Fig. 29 is an exploded perspective view of a cassette, which can form a part of the processing set used in association with the processing device shown in Figs. 1 and 2, and the pump and valve station on the processing device, which receives the cassette for use.

30 The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall  
35 within the meaning and range of equivalency of the claims

are therefore intended to be embraced by the claims.

#### Description of the Preferred Embodiments

Fig. 1 shows a fluid processing system 10 that embodies the features of the invention. The system 10  
5 can be used for processing various fluids.

The system 10 is particularly well suited for processing whole blood and other suspensions of biological cellular materials. Accordingly, the illustrated embodiment shows the system 10 used for this  
10 purpose.

#### I. System Overview

The system 10 includes three principal components. These are: (i) a liquid and blood flow set 12 (shown schematically in Fig. 3); (ii) a blood processing device  
15 14 (see Figs. 1 and 2), which interacts with the flow set 12 to cause separation and collection of one or more blood components; and (iii) a controller 16 carried on board the device 14, which governs the interaction to perform a blood processing and collection procedure  
20 selected by the operator.

#### A. The Processing Device and Controller

The blood processing device 14 and controller 16 are intended to be durable items capable of long term use. In the illustrated and preferred embodiment, the blood  
25 processing device 14 and controller 16 are mounted inside a portable housing or case 36. The case 36 presents a compact footprint, suited for set up and operation upon a table top or other relatively small surface. The case 36 is also intended to be transported easily to a collection  
30 site.

The case 36 includes a base 38 and a hinged lid 40, which opens for use (as Fig. 1 shows). In use, the base 38 is intended to rest in a generally horizontal support surface. The lid 40 also closes for transport (see Fig.  
35 26).

The case 36 can be formed into a desired configuration, e.g., by molding. The case 36 is preferably made from a lightweight, yet durable, plastic material.

5       The controller 16 carries out process control and monitoring functions for the system 10. The controller 16 comprises a main processing unit (MPU), which can comprise, e.g., a Pentium™ type microprocessor made by Intel Corporation, although other types of conventional  
10 microprocessors can be used. The MPU can be mounted inside the lid 40 of the case 36.

Preferably, the controller 16 also includes an interactive user interface 260, which allows the operator to view and comprehend information regarding the  
15 operation of the system 10. In the illustrated embodiment, the interface 260 includes an interface screen carried in the lid 40, which displays information for viewing by the operator in alpha-numeric format and as graphical images.

20       Further details of the controller 16 can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference. Further details of the interface can be found in Lyle et al, United States Patent 5,581,687, which is also incorporated herein by  
25 reference.

As Fig. 26 shows, the lid 40 can be used to support other input/outputs to couple other external devices to the controller 16 or other components of the device 14. For example, an ethernet port 50, or an input 52 for a  
30 bar code reader or the like (for scanning information into the controller 16), or a diagnostic port 54, or a port 56 to be coupled to a pressure cuff 58 (see Fig. 3), or a system transducer calibration port 60, can all be conveniently mounted for access on exterior of the lid  
35 40, or elsewhere on the case 36 of the device 14.

B. The Flow Set

The flow set 12 (see Fig. 3), is intended to be a sterile, single use, disposable item. Before beginning a given blood processing and collection procedure, the operator loads various components of the flow set 12 in the case 36 in association with the device 14 (as Figs. 1 and 2 show). The controller 16 implements the procedure based upon preset protocols, taking into account other input from the operator. Upon completing the procedure, the operator removes the flow set 12 from association with the device 14. The portion of the set 12 holding the collected blood component or components are removed from the case 36 and retained for storage, transfusion, or further processing. The remainder of the set 12 is removed from the case 36 and discarded.

The flow set 12 can take various forms. In the illustrated embodiment (see Figs. 1 and 3), the flow set includes a blood processing chamber 18 designed for use in association with a centrifuge. Accordingly, the processing device 14 includes a centrifuge station 20 (see Fig. 1), which receives the processing chamber 18 for use (see Fig. 12).

As Fig. 1 shows, the centrifuge station 20 comprises a compartment 21 formed in the base 38. The centrifuge station 20 includes a door 22, which opens and closes the compartment 21. The door 22 opens (as Fig. 1 shows) to allow loading of the processing chamber 18 into the compartment 21. The door 22 closes (as Fig. 2 shows) to enclose the processing chamber 18 within the compartment 21 during operation.

The centrifuge station 20 rotates the processing chamber 18. When rotated, the processing chamber 18 centrifugally separates whole blood received from a donor into component parts, e.g., red blood cells, plasma, and platelets.



In the illustrated embodiment, the set 12 also includes a fluid pressure actuated cassette 28 (see Fig. 29). The cassette 28 provides a centralized, programmable, integrated platform for all the pumping and valving functions required for a given blood processing procedure. In the illustrated embodiment, the fluid pressure comprises positive and negative pneumatic pressure. Other types of fluid pressure can be used.

The cassette 28 can take various forms. In a preferred embodiment (see Fig. 29), the cassette 28 comprises an injection molded body 200 made of a rigid medical grade plastic material. Flexible diaphragms 202, preferably made of flexible sheets of medical grade plastic, overlay the front side and back sides of the cassette 28. The diaphragms are sealed about their peripheries to the peripheral edges of the front and back sides of the cassette 28.

As Fig. 29 shows, the cassette 28 has an array of interior cavities formed on both the front and back sides. The interior cavities define pneumatic pump stations (schematically designated PS in Fig. 3), which are interconnected by a pattern of fluid flow paths (schematically designated FP in Fig. 3) through an array of in line, pneumatic valves (schematically designated V in Fig. 3).

As Figs. 1 and 29 show, the cassette 28 interacts with a pneumatic actuated pump and valve station 30, which is mounted in the lid of the 40 of the case 36. The pump and valve station 30 includes a cassette holder 216. A door 32 is hinged to move with respect to the cassette holder 216 between an opened position, exposing the cassette holder 216 (shown in Fig. 1) for loading and unloading the cassette 28, and a closed position, enclosing the cassette 28 within the pump and valve station 30 for use (shown in Fig. 2). The pump and valve

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station 30 includes pneumatic actuator ports 204 (see Fig. 29) that apply positive and negative pneumatic pressure upon the diaphragms of the cassette 28. The pneumatic pressures displace the diaphragms 202 with respect to the pump chambers and valves, to thereby direct liquid flow through the cassette 28.

Further details of the cassette 28 and the operation of the pump and valve station 30 can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

Referred back to Fig. 3, the flow set 16 also includes an array of tubes and containers in flow communication with the cassette 28. The arrangement of tubes and containers can vary according to the processing objectives. The system 10 can be operated to collect red blood cells, plasma, red blood cells and plasma, and platelets.

In the illustrated embodiment, the flow set 16 is arranged to support the centrifugal collection of two units of red blood cells (about 360 ml), and to filter the red blood cells to reduce the number of leukocytes prior to storage. During this procedure, whole blood from a donor is centrifugally processed in the chamber 18 into red blood cells (in which a majority of the leukocytes resides) and a plasma constituent (in which a majority of the platelets resides). The plasma constituent is returned to the donor, while the targeted volume of red blood cells is collected, filtered to reduce the population of leukocytes, and placed into containers for storage mixed with a red blood cell storage solution.

In this configuration (see Fig. 3), the flow set 16 includes a donor tube 266 having an attached phlebotomy needle 268. The donor tube 266 is coupled to a port of the cassette 28.

As Fig. 3 shows, a pressure cuff 58 is desirable used to enhance venous blood flow through the phlebotomy needle 268 during blood processing. The pressure cuff 58 is coupled to the pressure cuff port 56 on the lid 40 (as previously described), and the pressure supplied to the  
5 cuff 58 is desirably controlled by the controller 16. The controller 16 can also operate a vein pressure display 62 (see Fig. 26), which shows vein pressure at the pressure cuff 56.

10 An anticoagulant tube 270 is coupled to the phlebotomy needle 268. The anticoagulant tube 270 is coupled to another cassette port. A container 276 holding anticoagulant is coupled via a tube 274 to another cassette port.

15 A container 288 holding saline is coupled via a tube 284 to another cassette port.

The set 16 further includes tubes 290, 292, 294, which extend to an umbilicus 296. When installed in the processing station, the umbilicus 296 links the rotating  
20 processing chamber 18 with the cassette 28 without need for rotating seals. In a preferred embodiment, the umbilicus 296 is made from rotational-stress-resistant Hytrel® copolyester elastomers (DuPont). Further details of the construction of the umbilicus 296 will be provided  
25 later.

The tubes 290, 292, and 294 are coupled, respectively, to other cassette ports. The tube 290 conveys whole blood into the processing chamber 18. The tube 292 conveys plasma constituent from the processing  
30 chamber 18. The tube 294 conveys red blood cells from processing chamber 18.

A plasma collection reservoir 304 is coupled by a tube 302 to a cassette port. The collection reservoir 304 is intended, in use, to serve as a reservoir for the  
35 plasma constituent during processing prior to its return

to the donor.

A red blood cell collection reservoir 308 is coupled by a tube 306 to a cassette port. The collection reservoir 308 is intended, in use, to receive red blood  
5 cells during processing. for storage.

Two red blood cell storage containers 307 and 309 are coupled by a tube 311 to another cassette port. A leukocyte reduction filter 313 is carried in line by the tube 311. During processing, red blood cells are  
10 transferred from the red blood cell collection reservoir 308 through the filter 313 into the storage containers 307 and 309.

A container 208 holding a red blood cell storage or additive solution is coupled via a tube 278 to another  
15 cassette port. The red blood cell storage solution is metered into the red blood cells as they are conveyed from the container 308, through the filter 313, into the storage containers 307 and 309. Further details of this aspect of the collection process will be described later.

20 A whole blood reservoir 312 is coupled by a tube 310 to a cassette port. The collection container 312 is intended, in use, to serve as a reservoir for whole blood during processing.

In the illustrated embodiment, the set 16 further  
25 includes a fixture 338 (see Fig. 4) to hold the tubes 292 and 294 in viewing alignment with an optical sensing station 332 in the base 36 (see Fig. 12). The sensing station 332 optically monitors the presence or absence of targeted blood components (e.g., platelets and red blood  
30 cells) conveyed by the tubes 292 and 294. The sensing station 332 provides output reflecting the presence or absence of such blood components. This output is conveyed to the controller 16. The controller 16 processes the output and generates signals to control processing events  
35 based, in part, upon the optically sensed events. Further

details of the operation of the controller to control processing events based upon optical sensing can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

5       As Fig. 12 shows, the sensing station 332 is desirably located within the confines of the centrifuge station 20. This arrangement minimizes the fluid volume of components leaving the chamber before monitoring by the sensing station 332.

10       The fixture 338 gathers the tubes 292 and 294 in a compact, organized, side-by-side array, to be placed and removed as a group in association with the sensing station 332. In the illustrated embodiment, the fixture 338 also holds the tube 290, which conveys whole blood  
15       into the processing chamber 18, even though no associated sensor is provided. The fixture 338 serves to gather and hold all tubes 290, 292, and 294 that are coupled to the umbilicus 296 in a compact and easily handled bundle.

20       The fixture 338 can be an integral part of the umbilicus 296, formed, e.g., by over molding. Alternatively, the fixture 338 can be a separately fabricated part, which snap fits about the tubes 290, 292, and 294 for use.

25       As Figs. 1 and 2 also show, the case 36 contains other components compactly arranged to aid blood processing. In addition to the centrifuge station 20 and pump and valve station 30, already described, the case 36 includes a weigh station 238 and one or more trays 212 or hangers 248 for containers. The arrangement of these  
30       components in the case 36 can vary.

35       In the illustrated embodiment, the weigh station 238 comprises a series of container hangers/weigh sensors 246 arranged along the top of the lid 40. In use, the containers 304, 308, 312 are suspended on the hangers/weigh sensors 246.

The holding trays 212 comprise molded recesses in the base 38. The trays 212 accommodate the containers 276 (containing anticoagulant) and 208 (containing the red blood cell additive solution). In the illustrated embodiment, an additional swing-out side hanger 248 is also provided on the side of the lid 40. The hanger 248 (see Fig. 2) supports the container 288 (containing saline) during processing. Other swing out hangers 249 support the red blood cells storage containers 307 and 309.

In the illustrated embodiment, the tray 212 holding the container 276 and the hanger 248 also include weigh sensors 246.

As blood or liquids are received into and/or dispensed from the containers during processing, the weigh sensors 246 provide output reflecting weight changes over time. This output is conveyed to the controller 16. The controller 16 processes the incremental weight changes to derive fluid processing volumes. The controller generates signals to control processing events based, in part, upon the derived processing volumes. Further details of the operation of the controller to control processing events can be found in Nayak et al, United States Patent 6,261,065, which is incorporated herein by reference.

#### C. The Centrifugal Processing Chamber

Figs. 5 to 7 show an embodiment of the centrifugal processing chamber 18, which can be used in association with the system 10 shown in Fig. 1 to perform the intended red blood cell collection procedure. In the illustrated embodiment, the processing chamber 18 is preformed in a desired shape and configuration, e.g., by injection molding, from a rigid, biocompatible plastic material, such as a non-plasticized medical grade acrylonitrile-butadiene-styrene (ABS).

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In one arrangement, the chamber 18 can be fabricated in two separately molded pieces; namely (as Figs. 5 to 7 show), a base 388 and a lid 150. The base 388 includes a center hub 120. The hub 120 is surrounded radially by inside and outside annular walls 122 and 124. Between them, the inside and outside annular walls 122 and 124 define a circumferential blood separation channel 126. A molded annular wall 148 closes the bottom of the channel 126.

10       The top of the channel 126 is closed by the separately molded, flat lid 150 (which is shown separated in Fig. 5 for the purpose of illustration). During assembly (see Fig. 7), the lid 150 is secured to the top of the chamber 18, e.g., by use of a cylindrical sonic  
15       welding horn.

      All contours, ports, channels, and walls that affect the blood separation process may be preformed in the base 388 in a single, injection molded operation, during which molding mandrels are inserted and removed through the  
20       open end of the base 388 (shown in Fig. 5). The lid 150 comprises a simple flat part that can be easily welded to the open end of the base 388 to close it after molding. Because all features that affect the separation process are incorporated into one injection molded component, any  
25       tolerance differences between the base 388 and the lid 150 will not affect the separation efficiencies of the chamber 18.

      The contours, ports, channels, and walls that are preformed in the base 388 may create surfaces within the  
30       base 388 that do not readily permit the insertion and removal of molding mandrels through a single end of the base 388. In this arrangement, the base 388 can be formed by separate molded parts, either by nesting cup shaped subassemblies or two symmetric halves.

35       Alternatively, molding mandrels can be inserted and

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removed from both ends of the base 388. In this arrangement (see Fig. 8), the chamber 18 can be molded in three pieces; namely, the base 388, the lid 150 (which closes one end of the base 388 through which top molding  
5 mandrels are inserted and removed), and a separately molded insert 151 (which closes the other end of the base 388 through which bottom molding mandrels are inserted and removed).

The contours, ports, channels, and walls that are  
10 preformed in the base 388 can vary.

As seen in Fig. 9, in one arrangement, the inside annular wall 122 is open between one pair of stiffening walls. The opposing stiffening walls form an open interior region 134 in the hub 120, which communicates  
15 with the channel 126. Blood and fluids are introduced from the umbilicus 296 into and out of the separation channel 126 through this region 134.

In this embodiment (as Fig. 9 shows), a molded interior wall 136 formed inside the region 134 extends  
20 entirely across the channel 126, joining the outside annular wall 124. The wall 136 forms a terminus in the separation channel 126, which interrupts flow circumferentially along the channel 126 during separation.

25 Additional molded interior walls divide the region 134 into three passages 142, 144, and 146. The passages 142, 144, and 146 extend from the hub 120 and communicate with the channel 126 on opposite sides of the terminus wall 136. Blood and other fluids are directed from the  
30 hub 120 into and out of the channel 126 through these passages 142, 144, and 146.

The underside of the base 388 (see Fig. 7) includes a shaped receptacle 179. The far end of the umbilicus 296 includes a shaped mount 178 (see Figs. 24 and 24A). The  
35 mount 178 is shaped to correspond to the shape of the



receptacle 179. The mount 178 can thus be plugged into the receptacle 179 (as Fig. 7 shows), to couple the umbilicus 296 in fluid communication with the channel 126.

5       The mount 178 is desirably made from a material that can withstand considerable flexing and twisting, to which the mount 178 can be subjected during use, e.g., Hytrel® 3078 copolyester elastomer (DuPont). The dimensions of the shaped receptacle 179 and the shaped mount 178 are  
10       preferably selected to provide a tight, dry press fit, to thereby avoid the need for solvent bonding or ultrasonic welding techniques between the mount 178 and the base 388 (which can therefore be formed from an incompatible material, such as ABS plastic).

15       **D.     The Centrifuge Assembly**

      The centrifuge station 20 (see Fig. 10) includes a centrifuge assembly 48. The centrifuge assembly 48 is constructed to receive and support the molded processing chamber 18 and umbilicus 296 for use.

20       As illustrated (see Figs. 10 and 11), the centrifuge assembly 48 includes a yoke 154 having bottom, top, and side walls 156, 158, 160. The yoke 154 spins on a bearing element 162 (Fig. 11) attached to the bottom wall 156. An electric drive motor 164 is coupled to the bottom  
25       wall 156 of the yoke 154, to rotate the yoke 154 about an axis 64. In the illustrated embodiment, the axis 64 is essentially horizontal (see Fig. 1), although other angular orientations can be used.

      A rotor plate 166 (see Fig. 11) spins within the  
30       yoke 154 about its own bearing element 168, which is attached to the top wall 158 of the yoke 154. The rotor plate 166 spins about an axis that is generally aligned with the axis of rotation 64 of the yoke 154.

      As Fig. 7 best shows, the top of the processing  
35       chamber 18 includes an annular lip 380, to which the lid

150 is secured. As Fig. 12 shows, the rotor plate 166 includes a latching assembly 382 that removably grips the lip 380, to secure the processing chamber 18 on the rotor plate 166 for rotation.

5       The configuration of the latching assembly 382 can vary. In the illustrated embodiment (see Figs. 13 to 15), the latching assembly 382 includes a latch arm 66 pivotally mounted on a pin in a peripheral recess 68 in the rotor plate 166. The latch arm 66 pivots between a  
10   retaining position (shown in Figs. 13 and 14) and a releasing position (shown in Fig. 15).

      In the retaining position (see Fig. 14), an annular groove 70 on the underside of the latch arm 66 engages the annular lip 380 of the processing chamber 18. The  
15   annular groove 70 on the latch arm 66 coincides with an annular groove 71 that encircles the top interior surface of the rotor plate 166. The engagement of the lip 380 within the groove 70/71 secures the processing chamber 18 to the rotor plate 166.

20       In the releasing position (see Fig. 15), the annular groove 70 is swung free of engagement of the annular lip 380. This lack of engagement allows release of the processing chamber 18 from the remainder of the groove 71 in the rotor plate 166.

25       In the illustrated embodiment, the latching assembly 382 includes a sliding pawl 72 carried in a radial track 74 on the top of the rotor plate. In the track 74, the pawl 72 slides radially toward and away from the latch arm 66.

30       When the latch arm 66 is in its retaining position and the pawl 72 is located in a radial position adjacent the latch arm 66 (see Fig. 14), a finger 76 on the pawl 72 slips into and engages a cam recess 78 in the latch arm 66. The engagement between the pawl finger 76 and  
35   latch arm cam recess 78 physically resists movement of

the latch arm 66 toward the releasing position, thereby locking the latch arm 66 in the retaining position.

5 A spring 80 within the pawl 72 normally biases the pawl 72 toward this radial position adjacent the latch arm 66, where engagement between the pawl finger 76 and latch arm cam recess 78 can occur. The latch arm 66 is thereby normally held by the pawl 72 in a locked, retaining position, to hold the processing chamber 18 during use.

10 The pawl 72 can be manually moved against the bias of the spring 80 radially away from its position adjacent the latch arm 66 (see Fig. 15). During this movement, the finger 76 on the pawl 72 slips free of the cam recess 78 in the latch arm 66. Free of engagement between the pawl  
15 finger 76 and latch arm cam recess 78, the latch arm 66 is unlocked and can be pivoted toward its releasing position. In the absence of manual force against the bias of the spring 80, the pawl 72 returns by spring force toward its position adjacent the latch arm 66, to  
20 lock the latch arm 66 in the chamber retaining position.

In the illustrated embodiment (see Fig. 13), the top wall 158 of the yoke 154 carries a downward depending collar 82. The collar 82 rotates in unison with the yoke 154, relative to the rotor plate 166. The collar 82  
25 includes a sidewall 84 that is continuous, except for a cut away or open region 86.

As Fig. 17 best shows, the pawl 72 includes an upstanding key element 88. The sidewall 84 of the collar 82 is located in the radial path that the key element 88  
30 travels when the pawl 72 is manually moved against the bias of the spring 80 radially away from its position adjacent the latch arm 66. The key element 88 abuts against the collar sidewall 84, to inhibit movement of the pawl 72 in this direction, unless the open region 86  
35 is aligned with the key element 88, as shown in Figs. 13

and 15. The open region 86 accommodates passage of the key element 88, permitting manual movement of the pawl 72 against the bias of the spring 80 radially away from its position adjacent the latch arm 66, thereby allowing the  
5 latch arm 66 to pivot into its releasing position.

The interference between the collar sidewall 84 and the key element 88 of the pawl 72 prevents manual movement of the pawl 72 away from the latch arm 66, to unlock the latch arm 66 for movement into its releasing  
10 position, unless the open region 86 and the key element 88 register. The open region 86 is aligned on the yoke 154 so that this registration between the open region 86 and the key element 88 occurs only when the rotor plate 166 is in a prescribed rotational position relative to  
15 the yoke 154. In this position (see Fig. 12), the sidewalls 160 of the yoke 154 are located generally parallel to the plane of the opening to the compartment, providing open access to the interior of the yoke 154. In this position (see Fig. 16), the processing chamber 18  
20 can be freely placed without interference into the interior of the yoke 154, and loaded onto the rotor plate 166. In this position, uninhibited manual movement of the pawl 72 allows the operator to pivot the latch arm 66 into its releasing position, to bring the lid 150 of the  
25 chamber 18 into contact against the rotor plate 166. Subsequent release of the pawl 72 returns the pawl 72 toward the latch arm 66 and allows the operator to lock the latch arm 66 in its retaining position about the lip 380 of the chamber 18. The reverse sequence is  
30 accommodated when it is time to remove the processing chamber 18 from the rotor plate 166.

This arrangement makes possible a straightforward sequence of acts to load the processing chamber 18 for use and to unload the processing chamber 18 after use  
35 (see Fig. 16). As Figs. 17 and 18 further show, easy

loading of the umbilicus 296 is also made possible in tandem with fitting the processing chamber 18 to the rotor plate 166.

5 A sheath 182 on the near end of the umbilicus 296 fits into a preformed, recessed pocket 184 in the centrifuge station 20. The pocket 184 holds the near end of the umbilicus 296 in a nonrotating stationary position aligned with the mutually aligned rotational axes 64 of the yoke 154 and rotor plate 166.

10 The preformed pocket 184 is also shaped to accommodate loading of the fixture 338 at the same time the sheath 182 is inserted. The tubes 290, 292, and 294 are thereby placed and removed as a group in association with the sensing station 332, which is located within the  
15 pocket 184.

Umbilicus support members 186 and 187 (see Fig. 12) are carried by a side wall 160 of the yoke 154. When the rotor plate 166 is located in its prescribed rotational position to enable easy loading of the chamber 18 (see  
20 Figs. 17 and 18), the support members 186 and 187 are presented on the left side of the processing chamber 18 to receive the umbilicus 296 at the same time that the sheath 182 and fixture 338 are manipulated for fitting into the pocket 184.

25 As Fig. 19 shows, one member 186 receives the mid portion of the umbilicus 296. The member 186 includes a surface 188 against which the mid portion of the umbilicus 296 rests. The surface 188 forms a channel that extends generally parallel to the rotational axis 64 and  
30 that accommodates passage of the mid portion of the umbilicus 296. The surface 188 inhibits travel of the mid portion of the umbilicus 296 in radial directions toward and away from the rotational axis 64. However, the surface 188 permits rotation or twisting of the  
35 umbilicus 296 about its own axis.

The other member 187 receives the upper portion of the umbilicus 296. The member 187 includes a surface 190 against which the upper portion of the umbilicus 296 rests. The surface 190 forms a channel inclined toward the top wall 158 of the yoke 154. The surface 190 guides the upper portion of the umbilicus 296 toward the recessed pocket 184, which is located axially above the top wall 158 of the yoke 154, where the umbilicus sheath 182 and fixture 338 are fitted. Like the surface 188, the surface 190 inhibits travel of the upper portion of the umbilicus 296 in radial directions toward and away from the rotational axis 64. However, like the surface 188, the surface 190 permits rotation or twisting of the umbilicus 296 about its own axis.

Closing the centrifuge station door 20 positions a holding bracket 90 on the underside of the door 20 in registry with the sheath 182 (see Figs. 17 and 18). Another holding bracket 92 on the underside of the door 20 is positioned in registry with the fixture 338 when the door 20 is closed. A releasable latch 94 preferably holds the door shut during operation of the centrifuge assembly 48.

During operation of the centrifuge assembly 48 (see Figs. 19 to 22), the support members 186 and 187 carry the umbilicus 296 so that rotation of the yoke 154 also rotates the umbilicus 296 in tandem about the yoke axis. Constrained within the pocket 184 at its near end (i.e., at the sheath 182) and coupled to the chamber 16 at its far end (i.e., by the mount 178), the umbilicus 296 twists upon the surfaces 188 and 190 about its own axis as it rotates about the yoke axis 64, even as the surfaces 188 and 190 inhibit radial travel of the umbilicus relative to the rotation axis 64. The twirling of the umbilicus 296 about its axis as it rotates upon the surfaces 188 and 190 at one omega with the yoke 154

(typically at a speed of about 2250 RPM) imparts a two omega rotation to the processing chamber 18 secured for rotation on the rotor plate 166.

5 The relative rotation of the yoke 154 at a one omega rotational speed and the rotor plate 166 at a two omega rotational speed, keeps the umbilicus 296 untwisted, avoiding the need for rotating seals. The illustrated arrangement also allows a single drive motor 164 to impart rotation, through the umbilicus 296, to the  
10 mutually rotating yoke 154 and processing chamber 18 carried on the rotor plate 166. Further details of this arrangement are disclosed in Brown et al U.S. Patent 4,120,449, which is incorporated herein by reference.

15 The umbilicus 296 can stretch in response to the rotational forces it encounters. The dimensions of a given umbilicus 296 are also subject to normal manufacturing tolerances. These factors affect the flight radius of the umbilicus 296 during use; as well as the stress encountered by the mount 178 at the far end of the  
20 umbilicus 296, which serves as the two omega torque transmitter to drive the processing chamber 18; as well as the lateral loads acting on the centrifuge and motor bearings.

25 As Figs. 19 to 22 show, the support members 186 and 187 on the yoke serve to physically confine the flight of the umbilicus 296 between the one omega region (mid portion) and two omega region (far end portion), as well as between the one omega region (mid portion) and zero omega region (near end portion) of the umbilicus 296. By  
30 confining the umbilicus 296 to a predefined radial distance from and radial orientation with respect to the rotational axis of the centrifuge assembly 48, the support members 186 and 187 serve to attenuate the factors that can affect umbilicus performance and  
35 endurance.

The support members 186 and 187 make possible a bearing-less umbilicus assembly with no moving parts, while leading to reduced stress at the two omega torque region, where stresses tend to be greatest. The surfaces 188 and 190 of the support members 186 and 187 can be formed and oriented to accommodate rotation of the umbilicus 296 and the driving of the processing chamber 18 in either clockwise or counterclockwise directions.

In the illustrated embodiment, the surfaces 188 and 190 of the support members 186 and 187 are preferably fabricated from a low friction material, to thereby eliminate the need for external lubrication or rotating bearings on the umbilicus 296 itself. The material used can, e.g., comprise Teflon® polytetrafluoroethylene material (DuPont) or an ultra high molecular weight polyethylene. Made from such materials, the surfaces 188 and 190 minimize umbilicus drive friction and the presence of particulate matter due to umbilicus wear.

In a representative embodiment (see Fig. 4), the umbilicus 296 desirably comprises a two layer co-extruded assembly. The interior or core layer 96 desirably comprises Hytrel® 4056 copolyester elastomer (DuPont). The outside layer 98 desirably comprises Hytrel® 3078 copolyester elastomer (DuPont). The outside layer 98 may comprise a relatively thin extrusion, compared to the core layer 96.

In this arrangement, the outside layer 98 of Hytrel® 3078 copolyester elastomer serves as a compatible interface to accommodate over-molding of the zero omega sheath 182 and the two omega mount 178, which may comprise the same Hytrel® 3078 material or an otherwise compatible material. Absent material compatibility, solvents (e.g., methylene chloride) or other forms of surface treatment may be required to facilitate a robust bond between these elements and the umbilicus. Hytrel®



3078 material is desired for the sheath 182, and the mount 178 because it can withstand considerable flexing and twisting forces, to which these regions of the umbilicus are subjected during use.

5       The core layer 96 of Hytrel® 4056 copolyester elastomer can be readily solvent bonded to conventional flexible medical grade polyvinyl tubing, from which the tubes 290, 292, and 294 are desirably made.

## II. Double Red Blood Cell Collection Procedure

10       Use of the set 12 in association with the device 14 and controller 16 to conduct a typical double unit red blood cell collection procedure will now be described for illustrative purposes.

### A. The Cassette

15       The cassette 28 used for a procedure of this type desirably includes dual pneumatic pump chambers PP3 and PP4 (see Fig. 23) which are operated by the controller 16 in tandem to serve as a general purpose, donor interface pump. The dual donor interface pump chambers PP3 and PP4  
20 work in parallel. One pump chamber draws fluid, while the other pump chamber expels fluid. The dual pump chambers PP3 and PP4 thereby alternate draw and expel functions to provide a uniform outlet flow.

25       The cassette 28 also desirably includes a pneumatic pump chamber PP5, which serves as a dedicated anticoagulant pump, to draw anticoagulant from the container 276 and meter the anticoagulant into the blood drawn from the donor.

30       The cassette 28 also desirably includes a pneumatic pump chamber PP1 that serves as a dedicated in-process whole blood pump, to convey whole blood from the reservoir 312 into the processing chamber 18. The dedicated function of the pump chamber PP1 frees the donor interface pump chambers PP3 and PP4 from the added  
35 function of supplying whole blood to the processing

chamber 18. Thus, the in-process whole blood pump chamber PP1 can maintain a continuous supply of blood to the processing chamber 18, while the donor interface pump chambers PP3 and PP4 operate in tandem to simultaneously  
5 draw and return blood to the donor through the single phlebotomy needle. Processing time is thereby minimized.

The cassette 28 also desirably includes a pneumatic pump chamber PP2 that serves as a plasma pump, to convey plasma from the processing chamber 18. The ability to  
10 dedicate separate pumping functions provides a continuous flow of blood into and out of the processing chamber 18, as well as to and from the donor.

#### B. Capacitive Flow Sensing

The controller 16 desirably includes means for  
15 monitoring fluid flow through the pump chambers PP1 to PP5. In the illustrated embodiment, the pump and valve station 30 carries electrode circuits 206 associated with each pump chamber PP1 to PP5. The electrode circuits 206 can be located, e.g., within the pneumatic actuator ports  
20 204 in the pump and valve station 30 (see Fig. 29) that apply negative and positive pressure to the diaphragms to thereby draw fluid into the chambers PP1 to PP5 and expel fluid from the chambers PP1 to PP5. The electrode circuits 206 are coupled to an electrical source and are  
25 in electrical conductive contact with fluids within their respective pump chambers PP1 and PP5.

The passage of electrical energy through each electrode circuit 206 creates an electrical field within the respective pump chamber PP1 to PP5. Cyclic deflection  
30 of the diaphragm associated with a given pump chamber to draw fluid into and expel fluid from the pump chamber PP1 to PP5 changes the electrical field, resulting in a change in total capacitance of the circuit through the electrode. Capacitance increases as fluid is draw into  
35 the pump chamber PP1 to PP5, and capacitance decreases as

fluid is expelled from pump chamber PP1 to PP5.

In the arrangement, the electrode circuits 206 each includes a capacitive sensor (e.g., a Qprox E2S). The capacitive sensor registers changes in capacitance for the electrode circuit 206 for each pump chamber PP1 to PP5. The capacitance signal for a given electrode circuit 206 has a high signal magnitude when the pump chamber is filled with liquid, has a low signal magnitude signal when the pump chamber is empty of fluid, and has a range of intermediate signal magnitudes when the diaphragm occupies intermediate positions.

At the outset of a blood processing procedure, the controller 16 can calibrate the difference between the high and low signal magnitudes for each sensor to the maximum stroke volume of the respective pump chamber. The controller 16 can then relate the difference between sensed maximum and minimum signal values during subsequent draw and expel cycles to fluid volume drawn and expelled through the pump chamber. The controller 16 can sum the fluid volumes pumped over a sample time period to yield an actual flow rate.

The controller 16 can compare the actual flow rate to a desired flow rate. If a deviance exists, the controller 16 can vary pneumatic pressure pulses delivered to the actuators for the pump chambers PP1 to PP5 to minimize the deviance.

The controller 16 can also operate to detect abnormal operating conditions based upon the variations in the electric field and to generate corresponding alarm outputs. The controller 16 can, e.g., monitor for an increase in the magnitude of the low signal magnitude over time. The increase in magnitude reflects the presence of air inside a pump chamber.

For example, the controller 16 can generate a derivative of the signal output of the sensor 426.

Changes in the derivative, or the absence of a derivative, reflects a partial or complete occlusion of flow through the pump chamber PP1 to PP5. The derivative itself also varies in a distinct fashion depending upon  
5 whether the occlusion occurs at the inlet or outlet of the pump chamber PP1 to PP5.

1. Monitoring Vein Flow Conditions

By using capacitive sensing and by also counting pump strokes (i.e., the application of negative pressure  
10 upon the diaphragm of a given pump chamber to draw fluid into the chamber), the controller 16 can also monitor vein flow conditions, and, in particular, assess and respond to real or potential vein occlusion conditions.

When blood is pumped from the donor, the donor's  
15 vein may show difficulties in keeping up with the commanded draw rate that operation of the donor pump chambers PP3/PP4 imposes. In the case of restricted blood flow from the donor, the donor pumps PP3 and PP4 do not fill properly in response to the commanded sequence of  
20 pump strokes. The controller 16 attempts to assess and mediate blood supply interruptions due to vein problems before generating a vein occlusion alarm, which suspends processing.

For example, the controller 16 can count the number  
25 of consecutive attempted pump strokes for which no blood flow into the pump chambers PP3 and PP4 occurs (which blood flow or absence of blood flow can be detected by capacitive sensing, as above described). A potential donor draw occlusion condition can be deemed to occur  
30 when a prescribed number (e.g., 3) of consecutive incomplete fill donor pump strokes takes place.

When a potential donor draw occlusion condition is detected, the controller 16 attempts to rectify the condition by increasing pressure of the pressure cuff 58  
35 and/or decreasing the commanded draw rate, before

generating a processing-halting vein occlusion alarm.

More particularly, in a representative implementation, when a donor draw occlusion condition is detected, the controller 16 executes a potential draw  
5 occlusion condition function (in shorthand, the "Potential Occlusion Function"). The Potential Occlusion Function first suspends the draw for a period of time (e.g. upwards to 20 seconds, and desirably about 10 seconds) to rest the vein. While the vein rests, the  
10 controller 16 also increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg), unless cuff pressure, when adjusted, exceeds a prescribed maximum (e.g., upwards to 100 mmHg, desirably about 70 mmHg). If the prescribed  
15 maximum cuff pressure condition exists, no incremental changes to the cuff pressure are made during the prescribed vein rest interval.

After the prescribed vein rest interval, the Potential Occlusion Function resets the attempted pump  
20 stroke counter to zero and resumes the draw cycle. The controller 16 monitors the initial series of consecutive pump strokes during the resumed draw cycle, up to a first threshold number of pump strokes (e.g., 5). The magnitude of the first threshold number is larger than the number  
25 of consecutive incomplete fill donor pump strokes (i.e., 3) that indicate a potential donor draw occlusion condition. The magnitude of the first threshold number is selected to accurately assess, after a potential donor draw occlusion condition arises, whether a true donor draw  
30 occlusion exists. In the illustrated embodiment, if within the first five pump strokes (or whatever the first threshold number is), three consecutive incomplete fill donor pump strokes take place, the controller 16 assumes that a true donor draw occlusion exists, and thus  
35 generates an occlusion alarm. With the generation of an

occlusion alarm, the controller 16 suspends processing, until the operator can establish that it is safe to resume.

5 If within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes do not take place, the controller 16 assumes that a true vein occlusion may not exist, and that the potential occluded flow condition was either transient, or at least capable of correction short of suspending the  
10 procedure. In this event, the Potential Occlusion Function allows the resumed draw cycle to continue beyond the first threshold number of pump strokes up to a second threshold number of pump strokes (e.g., 20 to 100, and desirable about 50).

15 If at any time between the first threshold number of pump strokes and the second threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the Potential Occlusion Function institutes another vein rest interval(e.g. upwards to 20  
20 seconds, and desirably about 10 seconds). While the vein rests, the Potential Occlusion Function also again increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg). While the vein rests, the Potential Occlusion  
25 Function also lowers the draw rate by a preset decrement (e.g., upwards to 20 ml/min, and desirably about 10 ml/min). If the draw rate, when lowered, is less than a prescribed minimum draw rate (e.g., 70 to 90 ml/min), the controller 16 generates an occlusion alarm. Otherwise,  
30 the Potential Occlusion Function resets the attempted pump stroke counter to zero, and resumes the draw cycle at the increased cuff pressure and decreased draw rate.

The controller 16 again monitors the initial series of consecutive pump strokes during the resumed draw  
35 cycle, up to the first threshold number of pump strokes

(e.g., 5). If within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the controller 16 assumes that a true donor draw occlusion exists, and thus generates an occlusion alarm and also suspends processing.

However, if within the first threshold number of pump strokes, three consecutive incomplete fill donor pump strokes do not take place, the controller 16 allows the resumed draw cycle to continue beyond the first threshold number of pump strokes up to the second threshold number of pump strokes (e.g., 20 to 100, and desirable about 50). If at any time between the first threshold number of pump strokes and the second threshold number of pump strokes, three consecutive incomplete fill donor pump strokes take place, the Potential Occlusion Function again institutes another vein rest interval (e.g. upwards to 20 seconds, and desirably about 10 seconds). While the vein rests, the Potential Occlusion Function also again increases the pressure cuff pressure by a preset increment (e.g., upwards to 25mmHg, and desirably about 10 mmHg). While the vein rests, the Potential Occlusion Function also again lowers the draw rate by a preset decrement (e.g., upwards to 20 ml/min, and desirably about 10 ml/min), unless the draw rate, when lowered, is less than a prescribed minimum draw rate (e.g., 70 to 90 ml/min), in which case the controller 16 generates an occlusion alarm. Otherwise, the Potential Occlusion Function resets the attempted pump stroke counter to zero, and resumes the draw cycle at the increased cuff pressure and decreased draw rate.

The controller 16 continues to repeat the steps of the Potential Occlusion Function, using the first and second pump stroke number thresholds to gage whether a true vein occlusion exists, and either generating an occlusion alarm if it does, or continuing to attempt

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remedial action (by increasing cuff pressure and/or decreasing draw rate), or cancelling the potential donor draw occlusion condition when three consecutive incomplete fill donor pump strokes are not observed during either the first or second threshold periods following a potential donor occlusion condition.

If no three consecutive incomplete fill donor pump strokes take place within the second threshold number of strokes following a potential donor draw occlusion condition, the controller 16 assumes that a true vein occlusion does not exist. The draw cycle continues, and the controller 16 continues to count pump strokes. If the prescribed number (e.g., 3) of consecutive incomplete fill donor pump strokes subsequently takes place, the controller 16 assumes that this event is unrelated to any previous occlusion event condition, and generates a new potential donor draw occlusion condition, executing the Potential Occlusion Function from the start.

It should be appreciated that the Potential Occlusion Function, as just described, can be used with any blood processing device that has means for detecting when a draw blood pumping command does not result in blood flow through the pump.

#### C. Blood Processing Cycles

Prior to undertaking the double unit red blood cell collection procedure, as well as any blood collection procedure, the controller 16 conducts an appropriate integrity check of the cassette 28, to determine whether there are any leaks in the cassette 28. Once the cassette integrity check is complete and no leaks are found, the controller 16 begins the desired blood collection procedure.

In general, using the processing chamber shown in Fig. 9), whole blood is introduced into and separated within the processing chamber 18 as it rotates. As the



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processing chamber 18 rotates (arrow R in Fig. 9), the umbilicus 296 conveys whole blood into the channel 126 through the passage 146. The whole blood flows in the channel 126 in the same direction as rotation (which is counterclockwise in Fig. 9). Alternatively, the chamber 18 can be rotated in a direction opposite to the circumferential flow of whole blood, i.e., clockwise, but rotation in the same direction as circumferential blood flow is preferred.

10       The whole blood separates as a result of centrifugal forces. Red blood cells are driven toward the high-G wall 124, while lighter plasma constituent is displaced toward the low-G wall 122.       In this flow pattern, a dam 384 projects into the channel 126 toward the high-G wall 124. The dam 384 prevents passage of plasma, while allowing passage of red blood cells into a channel 386 recessed in the high-G wall 124. The channel 386 directs the red blood cells into the umbilicus 296 through the radial passage 144. The plasma constituent is conveyed from the channel 126 through the radial passage 142 into umbilicus 296.

#### 1. Collection Cycle

During a typical collection cycle of the double unit red blood cell collection procedure, whole blood drawn from the donor is processed to collect two units of red blood cells, while returning plasma to the donor. The donor interface pumps PP3/PP4 in the cassette, the anticoagulant pump P5 in the cassette, the in-process pump PP1 in the cassette, and the plasma pump PP2 in the cassette are pneumatically driven by the controller 16, in conjunction with associated pneumatic valves, to draw anticoagulated blood into the in-process container 312, while conveying the blood from the in-process container 312 into the processing chamber 18 for separation. This arrangement also removes plasma from the processing

chamber into the plasma container 304, while removing red blood cells from the processing chamber into the red blood cell container 308. This phase continues until an incremental volume of plasma is collected in the plasma collection container 304 (as monitored by a weigh sensor) or until a targeted volume of red blood cells is collected in the red blood cell collection container (as monitored by a weigh sensor).

If the volume of whole blood in the in-process container 312 reaches a predetermined maximum threshold before the targeted volume of either plasma or red blood cells is collected, the controller 16 terminates operation of the donor interface pumps PP3/PP4 to terminate collection of whole blood in the in-process container 312, while still continuing blood separation. If the volume of whole blood reaches a predetermined minimum threshold in the in-process container 312 during blood separation, but before the targeted volume of either plasma or red blood cells is collected, the controller 16 returns to drawing whole blood to thereby allow whole blood to enter the in-process container 312. The controller toggles between these two conditions according to the high and low volume thresholds for the in-process container 312, until the requisite volume of plasma has been collected, or until the target volume of red blood cells has been collected, whichever occurs first.

## 2. Return Cycle

During a typical return cycle (when the targeted volume of red blood cells has not been collected), the controller 16 operates the donor interface pumps PP3/PP4 within the cassette 28, the in-process pump PP1 within the cassette, and the plasma pump PP2 within the cassette, in conjunction with associated pneumatic valves, to convey anticoagulated whole blood from the in-

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process container 312 into the processing chamber 18 for separation, while removing plasma into the plasma container 304 and red blood cells into the red blood cell container 308. This arrangement also conveys plasma from the plasma container 304 to the donor, while also mixing saline from the container 288 in line with the returned plasma. The in line mixing of saline with plasma raises the saline temperature and improves donor comfort. This phase continues until the plasma container 304 is empty, as monitored by the weigh sensor.

If the volume of whole blood in the in-process container 312 reaches a specified low threshold before the plasma container 304 empties, the controller 16 terminates operation of the in-process pump PP1 to terminate blood separation. The phase continues until the plasma container 304 empties.

Upon emptying the plasma container 304, the controller 16 conducts another collection cycle. The controller 16 operates in successive collection and return cycles until the weigh sensor indicates that a desired volume of red blood cells have been collected in the red blood cell collection container 308. The controller 16 terminates the supply and removal of blood to and from the processing chamber, while operating the donor interface pumps PP3/PP4 in the cassette 28 to convey plasma remaining in the plasma container 304 to the donor. The controller 16 next operates the donor interface pumps PP3/PP4 in the cassette to convey the blood contents remaining in the in-process container 312 to the donor as well as convey saline to the donor, until a prescribed replacement volume amount is infused, as monitored by a weigh sensor.

### 3. . In-Line Leukofiltration Cycle

When the collection of red blood cells and the return of plasma and residual blood components has been

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completed, the controller 16 switches, either automatically or after prompting the operator, to an in-line leukofiltration cycle. During this cycle, red blood cells are removed from the red blood cell collection reservoir 308 and conveyed into the red blood cell storage containers 307 and 308 through the leukocyte removal filter 313. At the same time, a desired volume of red blood cell storage solution from the container 208 is mixed with the red blood cells.

10 In the first stage of this cycle, the controller 16 operates donor interface pumps PP3/PP4 in the cassette to draw air from the red blood cell storage containers 307 and 309, the filter 313, and the line 311, and to transfer this air into the red blood cell collection reservoir 308. This stage minimizes the volume of air residing in the red blood cell storage containers 307 and 309 before the leukocyte removal process begins. The stage also provides a volume of air in the red blood cell collection container 308 that can be used purge red blood cells from the filter 313 into the red blood cell collection containers 307 and 309 once the leukocyte removal process is completed.

25 In the next stage, the controller 16 operates the donor interface pumps PP3/PP4 in the cassette 28 to draw a priming volume of storage solution from the solution container 208 into the red blood cell collection reservoir 308. This stage primes the tubing 278 between the container 208 and the cassette 28, to minimize the volume of air pumped into the final red blood cell storage containers 307 and 309.

30 In the next stage, the controller 16 operates the donor interface pumps PP3/PP4 in the cassette 28 to alternate pumping red blood cells from the red blood cell collection reservoir 308 into the red blood cell collection containers 307 and 309 (through the filter

313), with pumping of red blood cell storage solution from the container 208 into the red blood cell collection containers 307 and 309 (also through the filter 313). This alternating process mixes the storage solution with  
5 the red blood cells. The controller 16 counts the pneumatic pump strokes for red blood cells and the storage solution to obtain a desired ratio of red cell volume to storage solution volume (e.g., five pump strokes for red blood cells, followed by two pump strokes  
10 for storage solution, and repeating the alternating sequence). This alternating supply of red blood cells and storage solution continues until the weigh scale for the red blood cell collection reservoir 308 indicates that the reservoir 308 is empty.

15 When the red blood cell collection reservoir 308 is empty, the controller 16 operates the donor interface pumps PP3/PP4 to pump additional storage solution through the filter 313 and into the red blood storage containers 307 and 309, to ensure that a desired ratio between  
20 storage solution volume and red blood cell volume exists. This also rinses residual red blood cells from the filter 313 into the red blood cell storage containers 307 and 309 to maximize post-filtration percent red blood cell recovery.

25 The controlled ratio of pump strokes for red blood cells and for storage solution that the controller 16 achieves ensures that the storage solution is always metered in at a constant ratio. Therefore, regardless of the volume of red blood cells collected, the final red  
30 blood cell / storage solution hematocrit can be constant.

The alternating supply of red blood cells and storage solution through the filter 313 eliminates the need to first drain the storage solution into the red blood cell collection reservoir 308, which lessens the  
35 overall procedure time.

The alternating supply of red blood cells and storage solution through the filter 313 also eliminates the need to manually agitate a red blood cell / storage solution mixture prior to leukofiltration. Due to  
5 density differences, when concentrated red blood cells are added to a preservation solution, or vice versa, the preservation solution floats to the top. Poorly mixed, high hematocrit, high viscosity red blood cells lead to reduced flow rates during leukofiltration. Poorly mixed,  
10 high hematocrit, high viscosity red blood cell conditions can also lead to hemolysis. By alternating passage of red blood cells and storage solution through the filter 313, mixing occurs automatically without operator involvement.

15 The alternating supply of red blood cells and storage solution through the filter 313 also eliminates the need to gravity drain the red blood cell product through the leukofilter 313. As a result, filtration can occur in about half the time required for a gravity-drain  
20 procedure.

If desired, the controller 16 can monitor weight changes relating to the red blood cell collection reservoir 308 and the red blood cell storage containers 307 and 309, to derive a value reflecting the percent of  
25 red blood cells that are recovered after passage through the leukofilter 313. This value can be communicated to the operator, e.g., on the display screen of user the user interface.

The following expression can be used to derive the  
30 percent recovery value:

$$\% \text{ Recovery} = [(\text{Bag A Vol} + \text{Bag B Vol}) / \text{RBC Vol} + \text{Adsol}] * 100$$

where:

Bag A Vol represents the volume of red blood cells  
35 collected the container 307, calculated as follows:

(Wt of Container 307 containing red blood cells (in g) - Container 307 Tare) / 1.062 g/ml

Bag B Vol represents the volume of red blood cells collected the container 309, calculated as follows:

5 (Wt of Container 309 containing red blood cells (in g) - Container 309 Tare) / 1.062 g/ml

RBC Vol represents the volume of red blood cells collected in the red blood cell collection reservoir 308, which the controller 16 determines by weight sensing at  
10 the end of the procedure.

Adsol represents the volume of red blood cell storage solution added to the during leukofiltration, which is determined by the controller 16 by capacitive sensing during processing.

15 a. The Leukofilter

The leukofilter 313 can be variously constructed. In the embodiment illustrated in Figs. 24A and 24B, the filter comprises a housing 100 inclosing a filtration medium 102 that can comprise a membrane or be made from a  
20 fibrous material. The filtration medium 102 can be arranged in a single layer or in a multiple layer stack. If fibrous, the medium 102 can include melt blown or spun bonded synthetic fibers (e.g., nylon or polyester or polypropylene), semi-synthetic fibers, regenerated  
25 fibers, or inorganic fibers. If fibrous, the medium 102 removes leukocytes by depth filtration. If a membrane, the medium 102 removes leukocytes by exclusion.

The housing 100 can comprise rigid plastic plates sealed about their peripheries. In the illustrated  
30 embodiment, the housing 100 comprises first and second flexible sheets 104 of medical grade plastic material, such as polyvinyl chloride plasticized with di-2-ethylhexyl-phthalate (PVC-DEHP). Other medical grade plastic materials can be used that are not PVC and/or are  
35 DEHP-free.

In the illustrated embodiment, a unitary, continuous peripheral seal 106 (see Fig. 24B) is formed by the application of pressure and radio frequency heating in a single process to the two sheets 104 and filtration medium 102. The seal 106 joins the two sheets 104 to each other, as well as joins the filtration medium 102 to the two sheets 104. The seal 106 integrates the material of the filtration medium 102 and the material of the plastic sheets 104, for a reliable, robust, leak-proof boundary. Since the seal 106 is unitary and continuous, the possibility of blood shunting around the periphery of the filtration medium 102 is eliminated.

The filter 313 also includes inlet and outlet ports 108. The ports 108 can comprise tubes made of medical grade plastic material, like PVC-DEHP. In the embodiment shown in Fig. 24, the ports 108 comprise separately molded parts that are heat sealed by radio frequency energy over a hole 109 formed in the sheets 104 (see Fig. 24B).

In the illustrated embodiment (as Figs. 25A and 25B show), the filter 313 is desirably placed within a restraining fixture 110 during use. The fixture 110 restrains expansion of the flexible sheets 104 of the filter housing 100 as a result of pressure applied by pumping red blood cells through the filter 313. The fixture 110 keeps the total blood volume in the filter 313 at a minimum through the filtration process, thereby decreasing filtration time, as well as increasing the red blood cell recovery percentage following leukofiltration.

The fixture 110 can take various forms. In the illustrated embodiment, the fixture 110 comprises two plates 112 coupled by a hinge 114. The fixture 110 can be placed in an open condition (as Fig. 25A shows) to receive the filter 313 prior to leukofiltration, or to remove the filter 313 following leukofiltration. The



fixture 110 can also be placed in a closed condition (as Fig. 25B shows) to sandwich the filter 313 between the two plates 112. A releasably latch 116 holds the plates 112 in the closed condition for use.

5       The plates 112 maintain a desired gap clearance, thereby restraining expansion of the filter 313 during use. The gap clearance is selected to maintain a desired blood flow rate at a desired minimum blood volume.

10       The plates 112 desirably include indentations 118 in which the ports 108 of the filter 313 rest in a non-occluded condition when the fixture 110 is closed. The interior surfaces of the plates 112 may be roughed or scored with a finish to aid blood flow through the filter 313 when the fixture 110 is closed.

15       The fixture 110 can be made as a stand-alone item that can be separately stored prior to use. It can be stored in association with the device 14 during transport and prior to use, e.g., in a receptacle 128 formed on the exterior of the lid 40 of the device 14 (see Fig. 26).  
20       The fixture 110 can include a mounting bracket 130 (see Fig. 28) that, e.g., slidably engages a mating mounting track 132, to hold the fixture 110 in the receptacle 128 prior to use (shown in phantom lines in Fig. 26) or to secure the fixture 110 on the base 38 as leukofiltration  
25       is carried out (see Fig. 27).

      It should be appreciated that pump-assisted leukofiltration of red blood cells, whole blood, or other blood cell products, wherein blood flow through a leukofilter is not driven strictly by gravity flow, can  
30       be carried out using manual or automated systems having configurations different than those shown in this Specification. For example, external peristaltic or fluid actuated pumping devices can be used to transfer whole blood or manually processed blood products from  
35       separation bags into processing or storage containers

through intermediate leukofiltration devices. It should also be appreciated that a filter restraining fixture of the type shown in Fig. 24B can also be used in association with any pump-assisted leukofiltration system. It should also be appreciated that a filter restraining fixture 110 can also be used in systems where blood flow through the leukofilter relies strictly upon gravity flow.

5 The many features of the invention have been demonstrated by describing their use in separating whole blood into component parts for storage and blood component therapy. This is because the invention is well adapted for use in carrying out these blood processing procedures. It should be appreciated, however, that the features of the invention equally lend themselves to use in other blood processing procedures.

10 For example, the systems and methods described, which make use of a programmable cassette in association with a blood processing chamber, can be used for the purpose of washing or salvaging blood cells during surgery, or for the purpose of conducting therapeutic plasma exchange, or in any other procedure where blood is circulated in an extracorporeal path for treatment.

20 Features of the invention are set forth in the following claims.

We Claim:

1. A blood processing system comprising  
a blood processing set including a source of  
blood cells, and a blood component collection flow  
5 channel coupled to the source of blood cells including a  
blood cell storage container and an in-line filter to  
remove leukocytes from the blood cells before entering  
the blood cell storage container, the in-line filter  
including a fibrous filter medium, first and second  
10 flexible housings, a unitary, continuous peripheral seal  
formed by application of pressure and radio-frequency  
heating in a single process to join the first and second  
flexible housings to each other, as well as join the  
fibrous filtration medium to the first and second  
15 flexible housings, and

a pump station adapted to be placed into  
communication with the blood component collection flow  
channel to pump blood into the blood cell storage  
container through the in-line filter.

20 2. A blood processing system according to  
claim 1

further including a fixture to restrain  
expansion of the first and second filter housings as a  
result of pressure applied during operation of the pump  
25 station.

3. A blood processing system according to  
claim 2

wherein the source of blood cells includes a  
donor flow channel including a blood separation device to  
30 separate blood cells from donor whole blood.

4. A blood processing system according to  
claim 1

wherein the source of blood cells includes a  
donor flow channel including a blood separation device to  
35 separate blood cells from donor whole blood.

- 45 -

5. A system according to claim 1 or 2 or 3  
or 4

wherein the controller includes a function to  
derive a value reflecting volume of blood cells present  
5 in the blood cell storage container after passage through  
the filter as a percentage of volume of blood cells  
conveyed to the filter.

6. A system according to claim 1 or 2 or 3  
or 4

10 wherein the pump station includes a fluid  
pressure actuated pump and an actuator to apply fluid  
pressure to the pump.

7. A system according to claim 1 or 2 or 3  
or 4

15 wherein the blood cells comprise red blood  
cells.

8. A method of processing blood comprising  
using the blood processing system as defined in claim 1  
or 2 or 3 or 4.

20

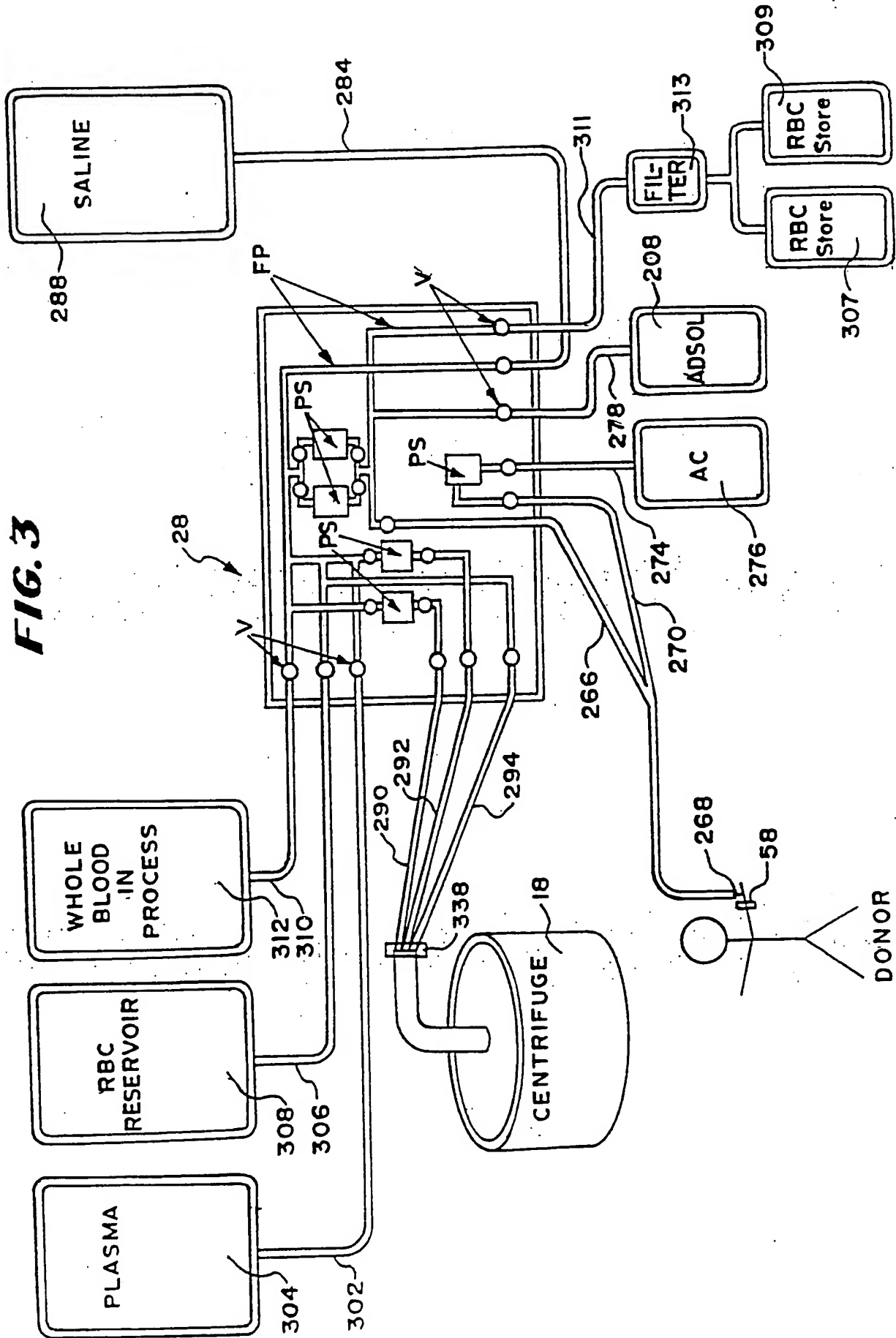
**ABSTRACT**

Systems and methods separate pump the blood cells through an in-line leukofilter to a blood cell storage container. The leukofilter has a filtration medium enclosed within a flexile housing. The systems and methods can employ a fixture to restrain expansion of the flexible filter housing during operation of the pump.



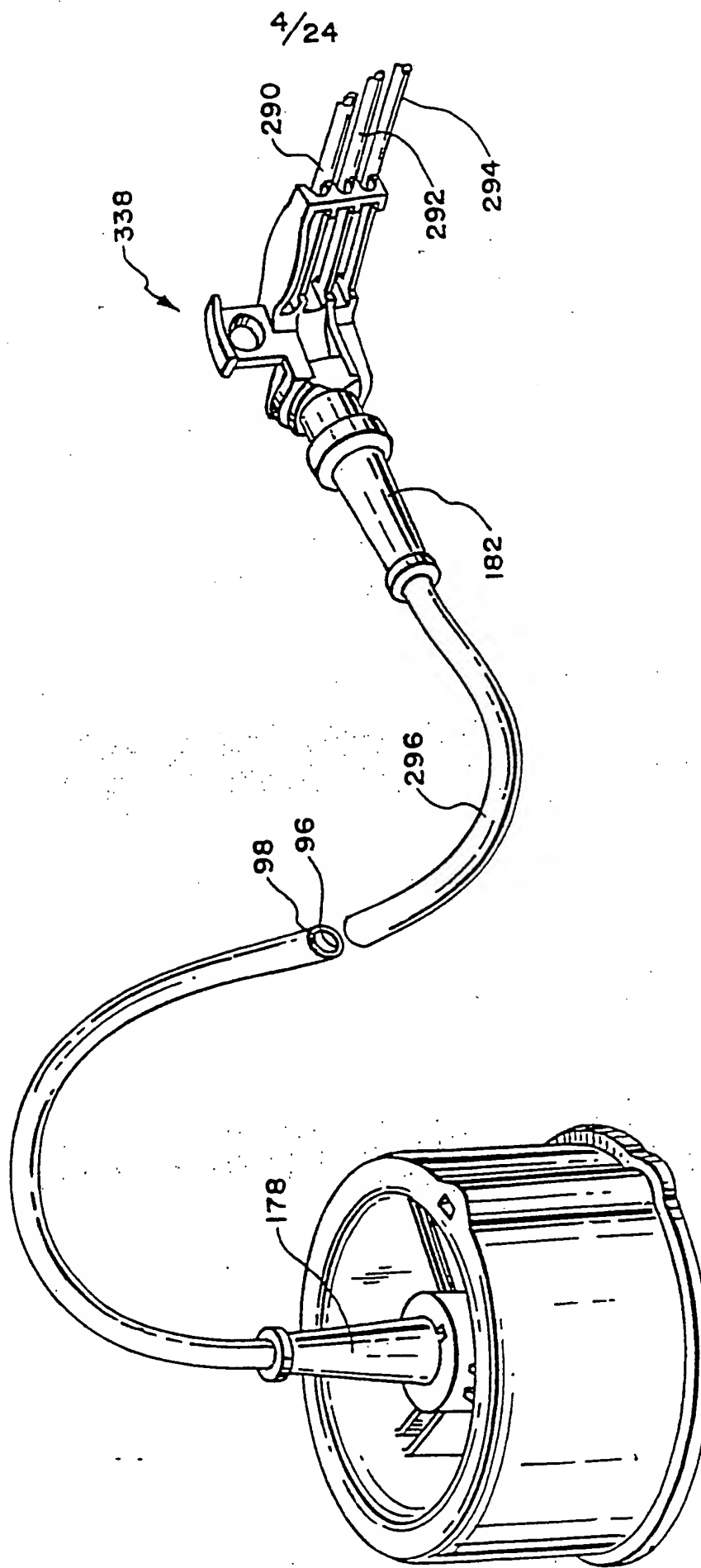


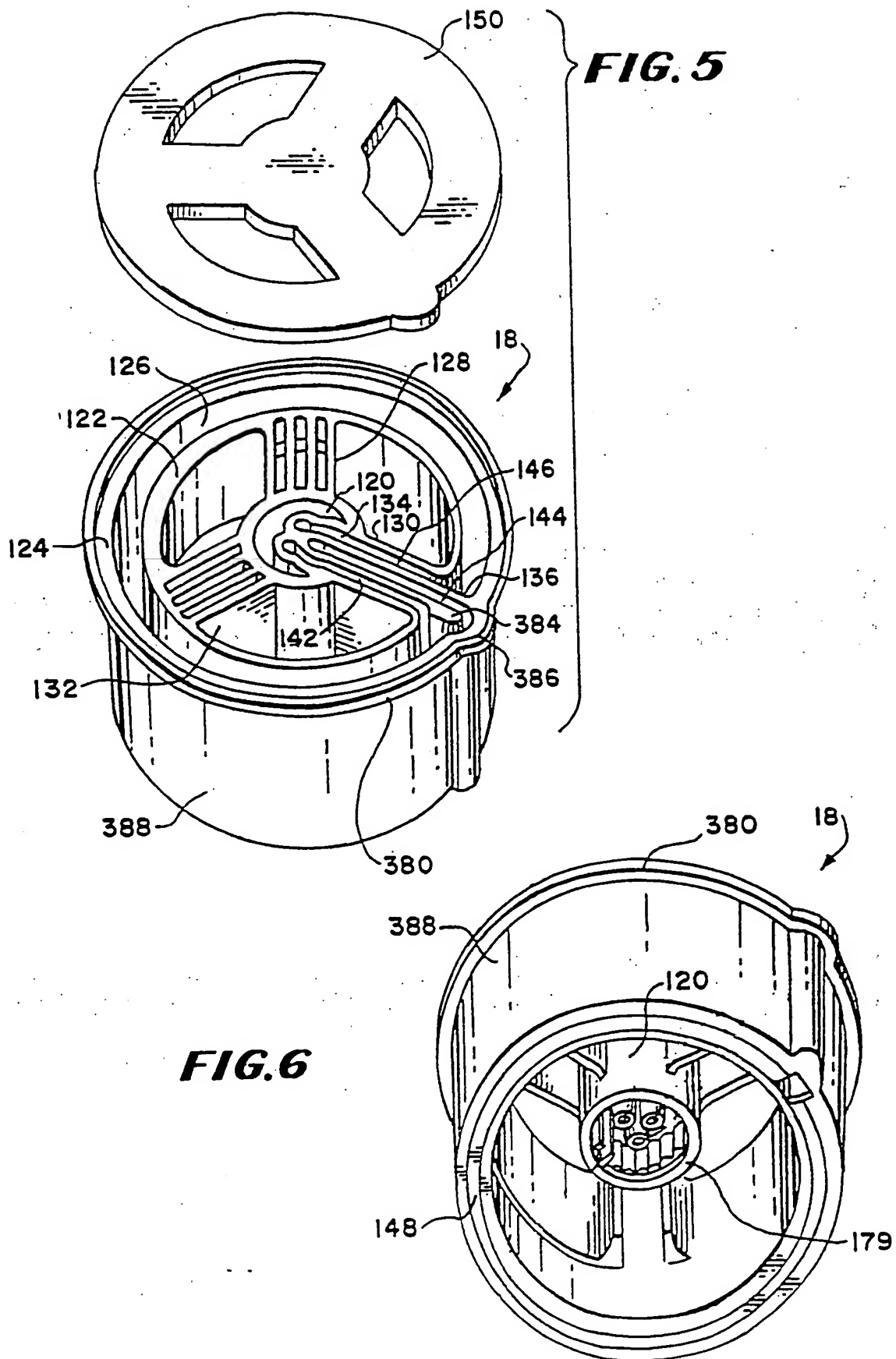
FIG. 3

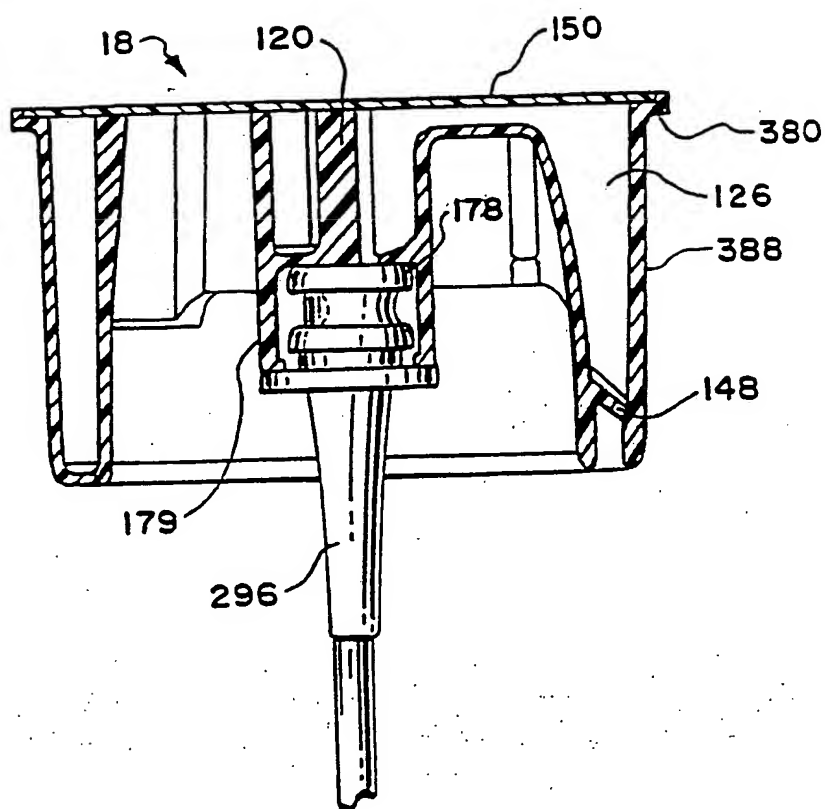
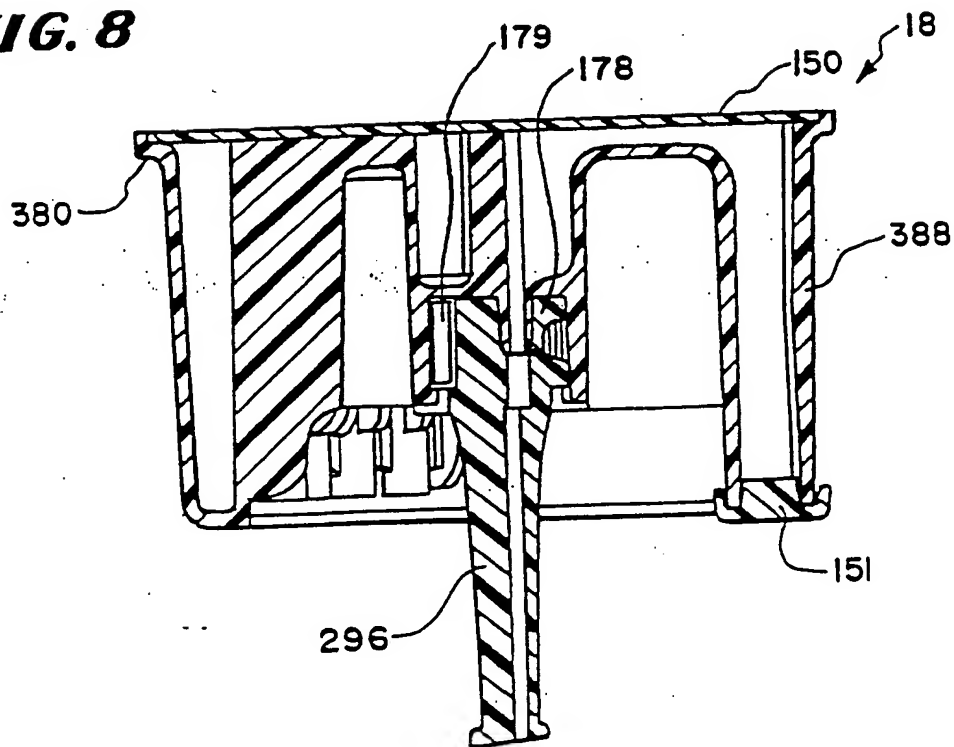


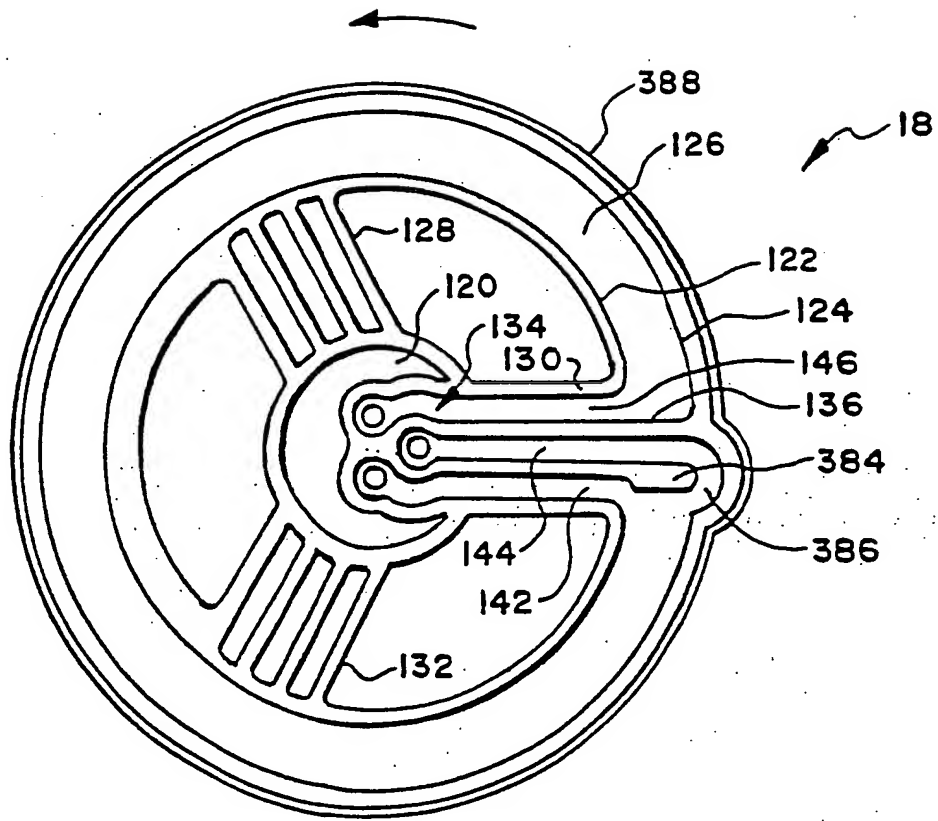


**FIG. 4**

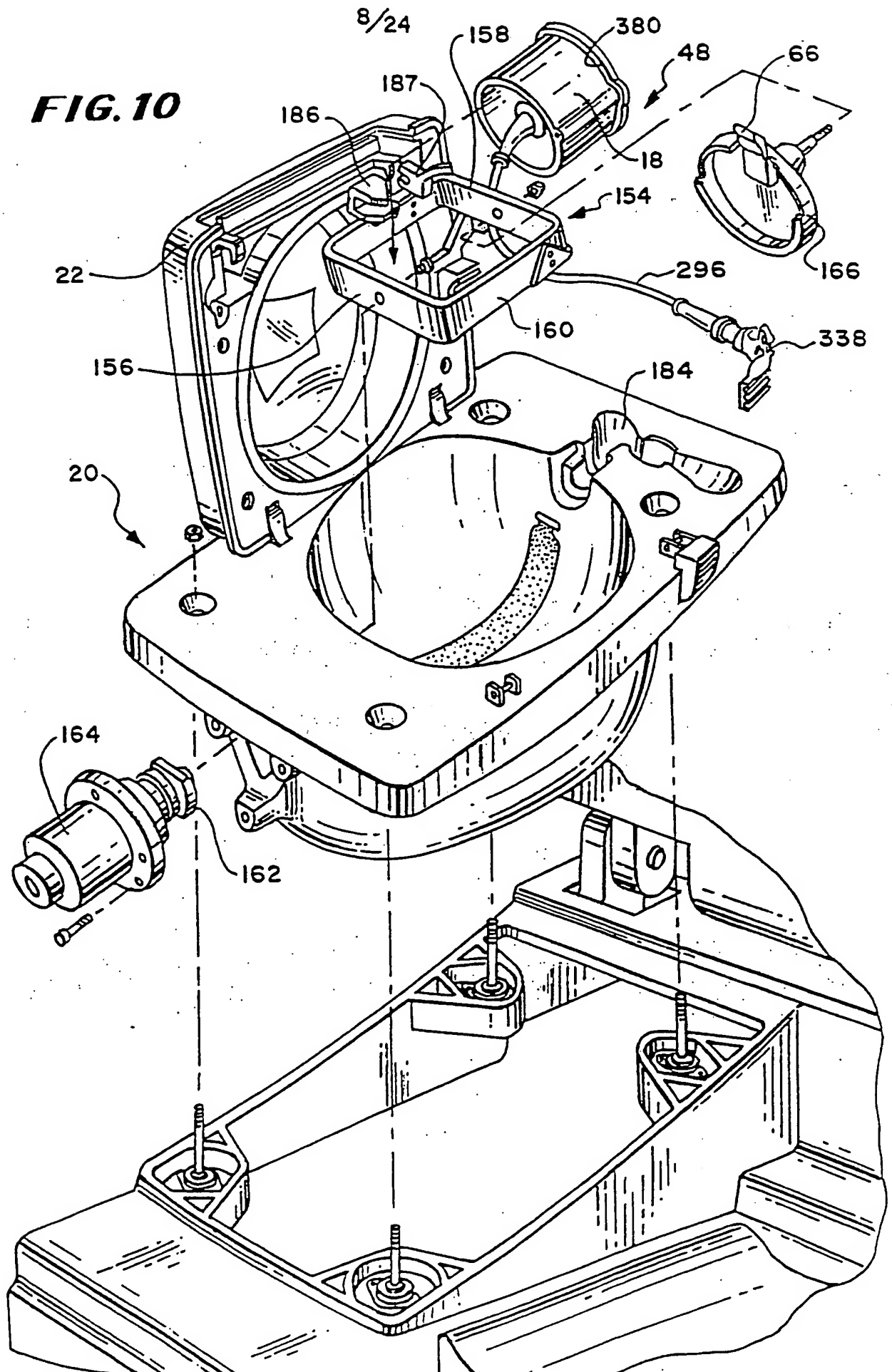




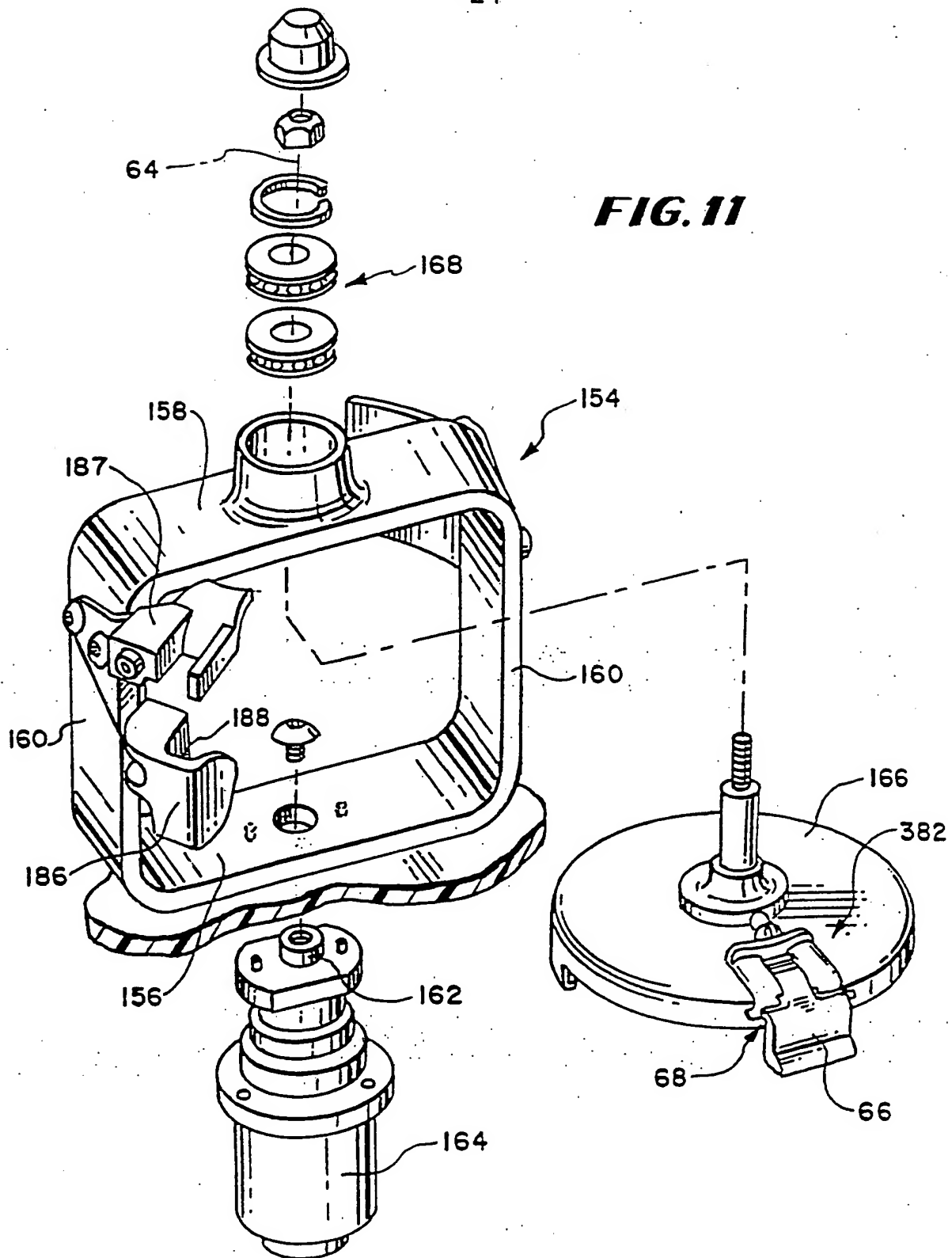
**FIG. 7****FIG. 8**

**FIG. 9**

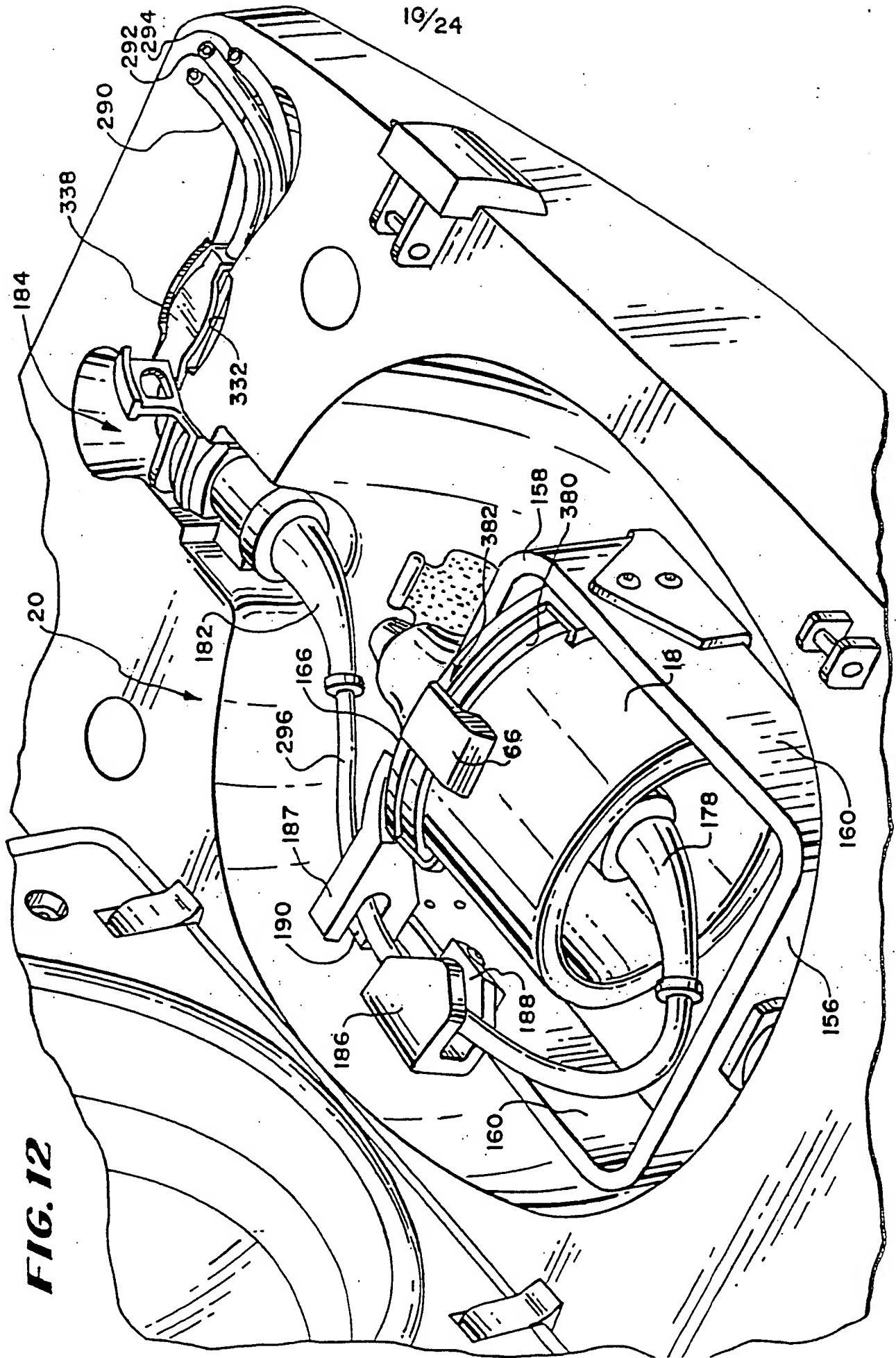
**FIG. 10**

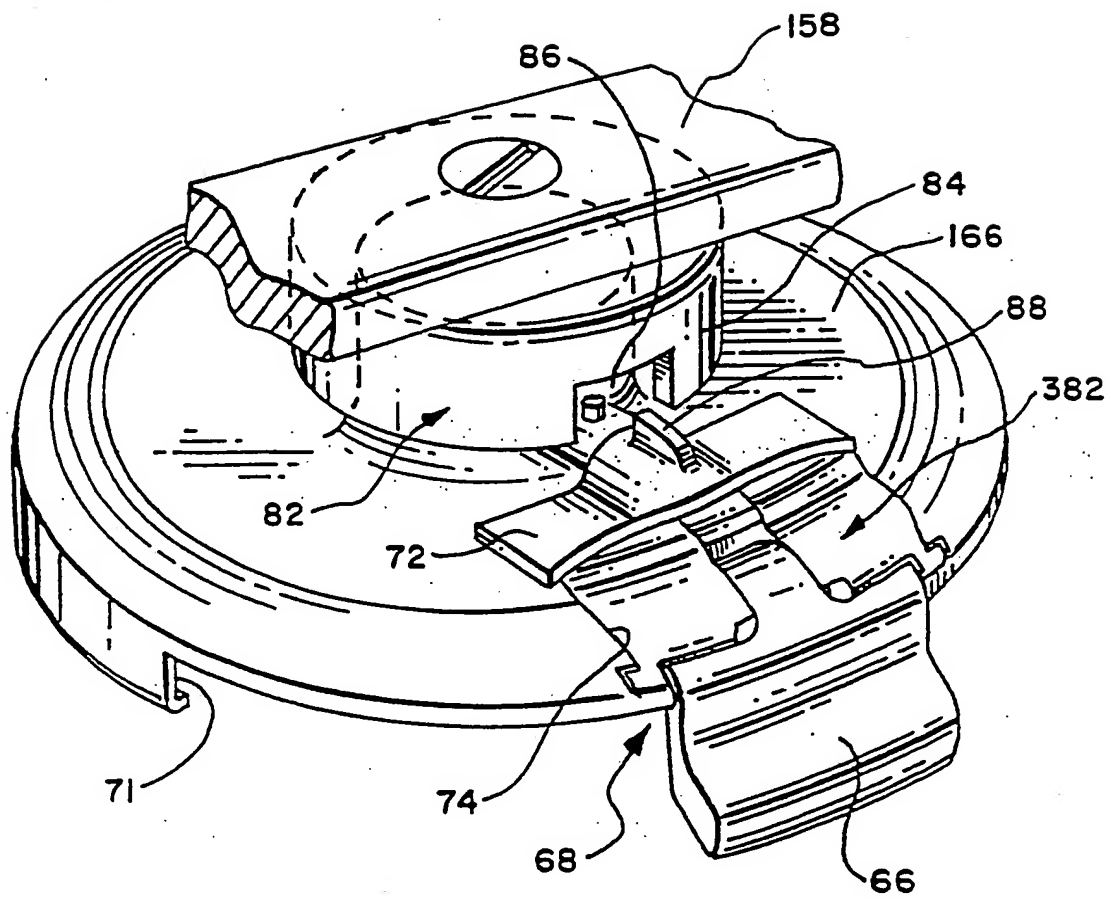


9/24



**FIG. 12**



**FIG. 13**



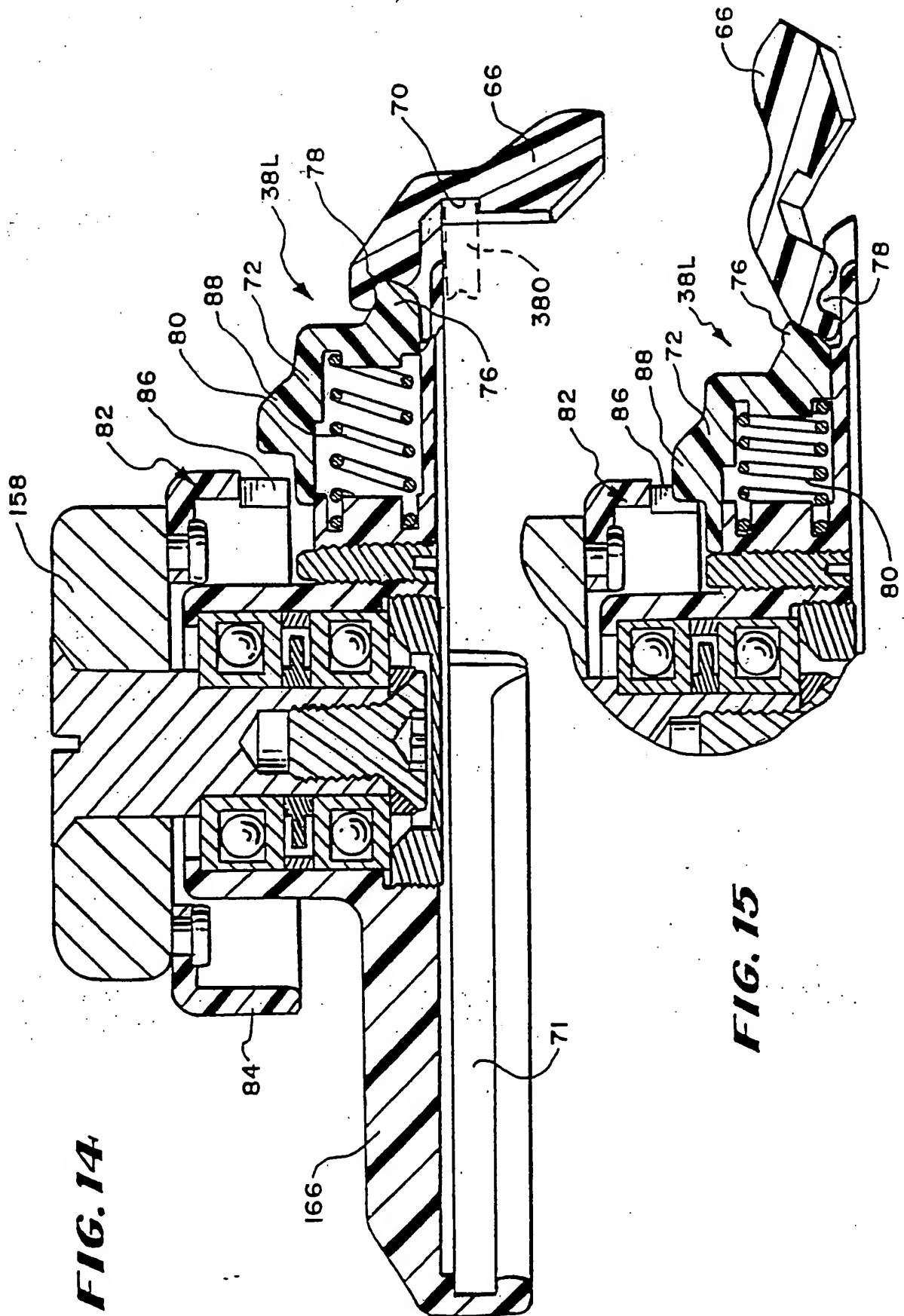
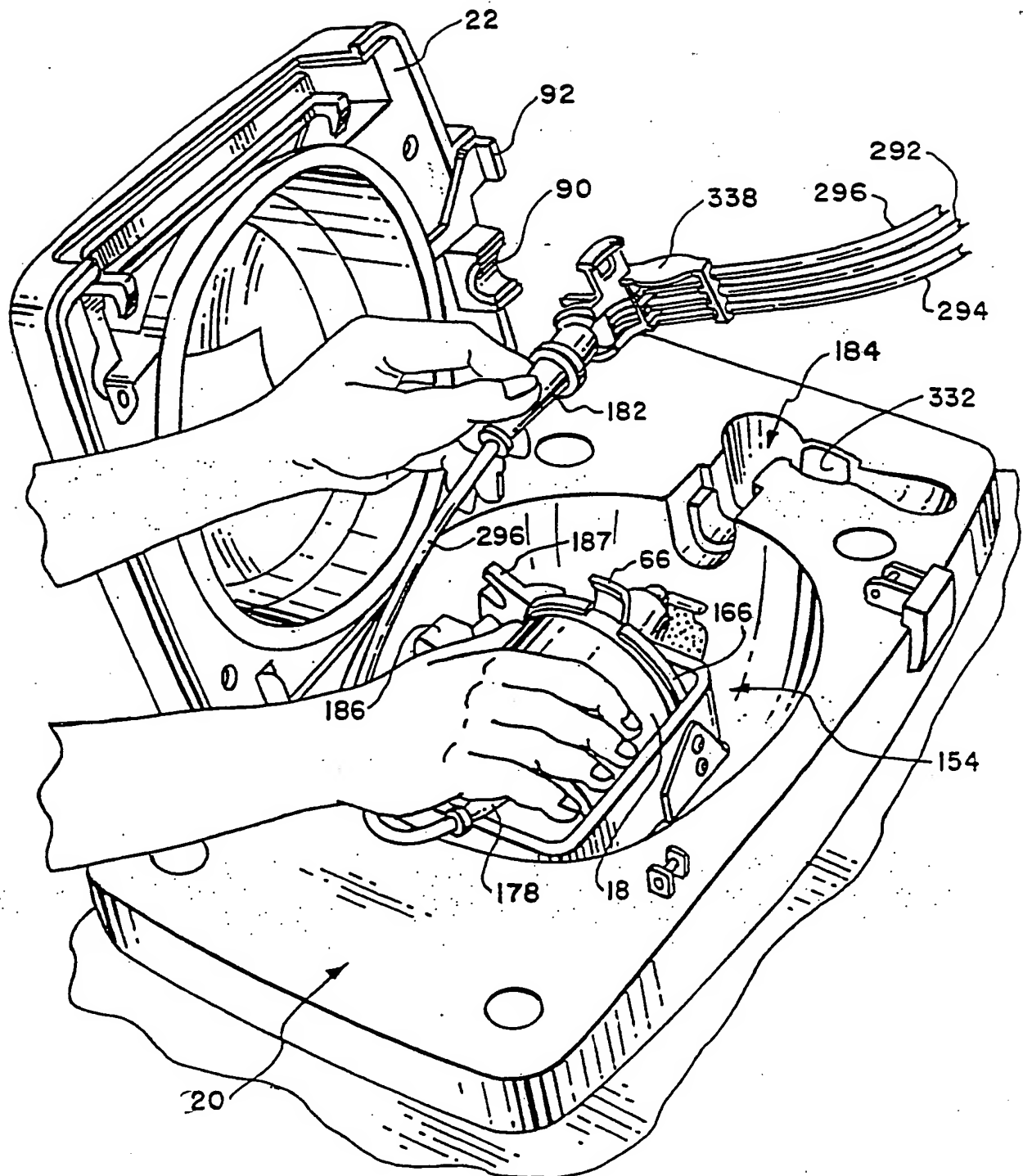
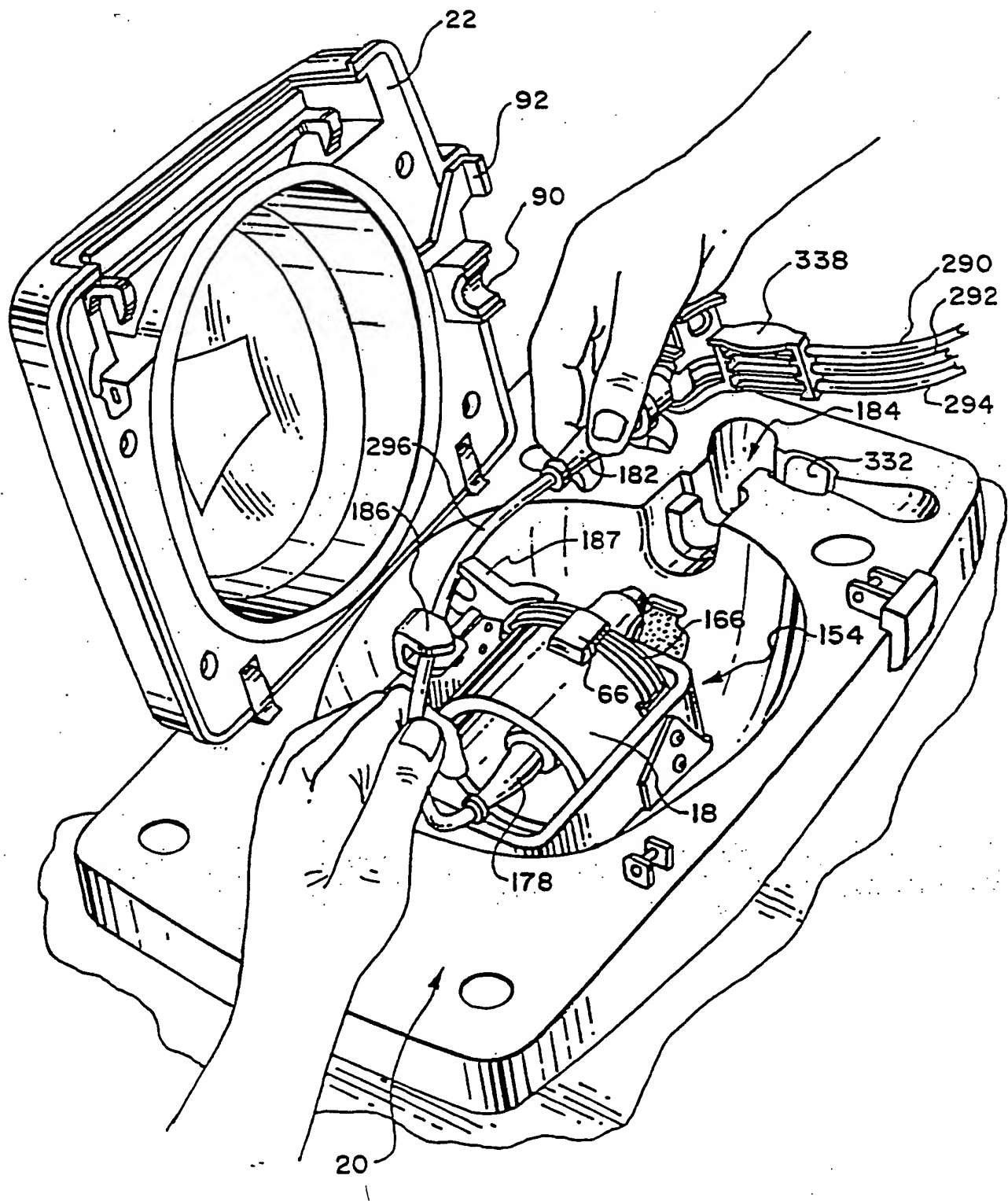


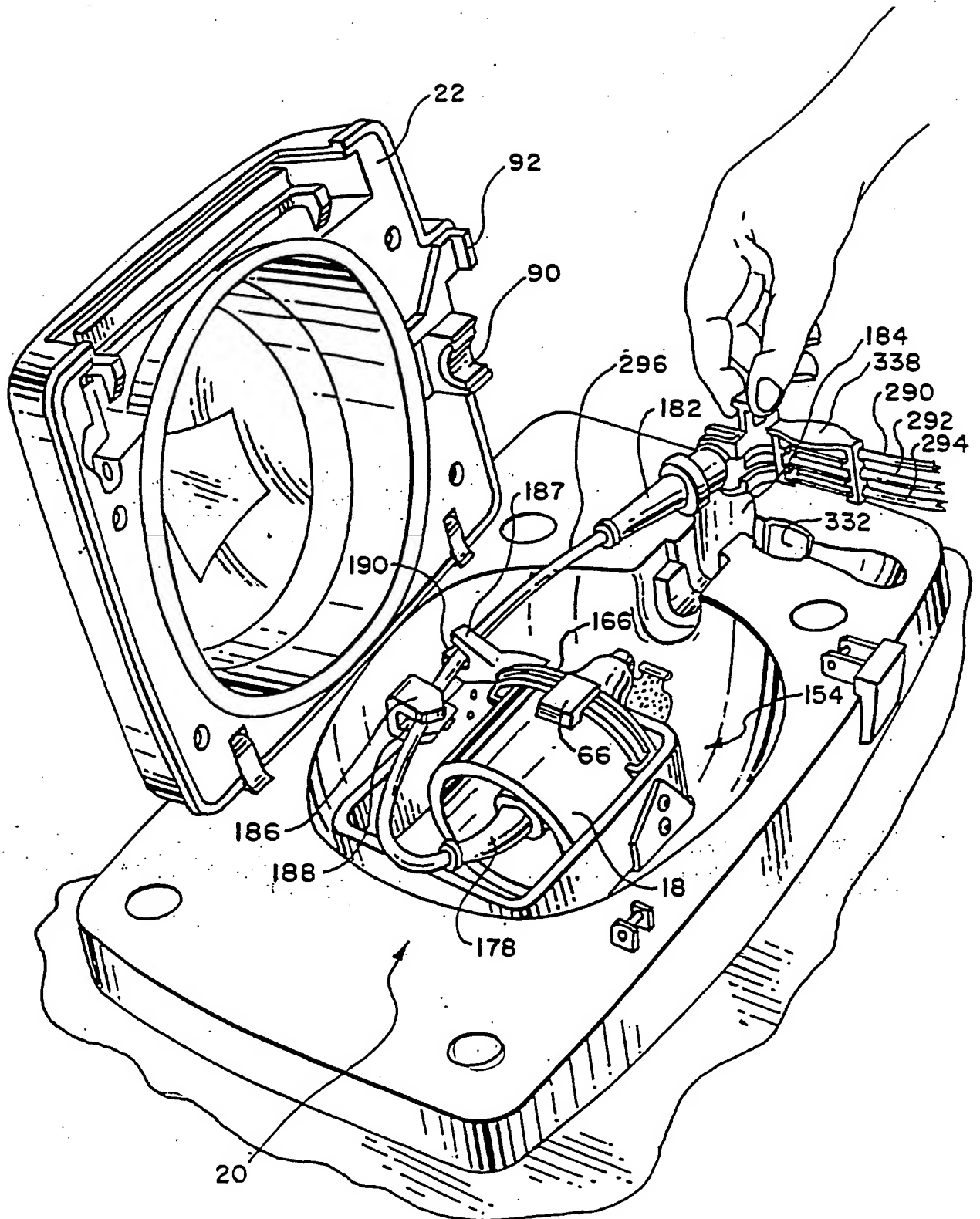
FIG. 14

FIG. 15

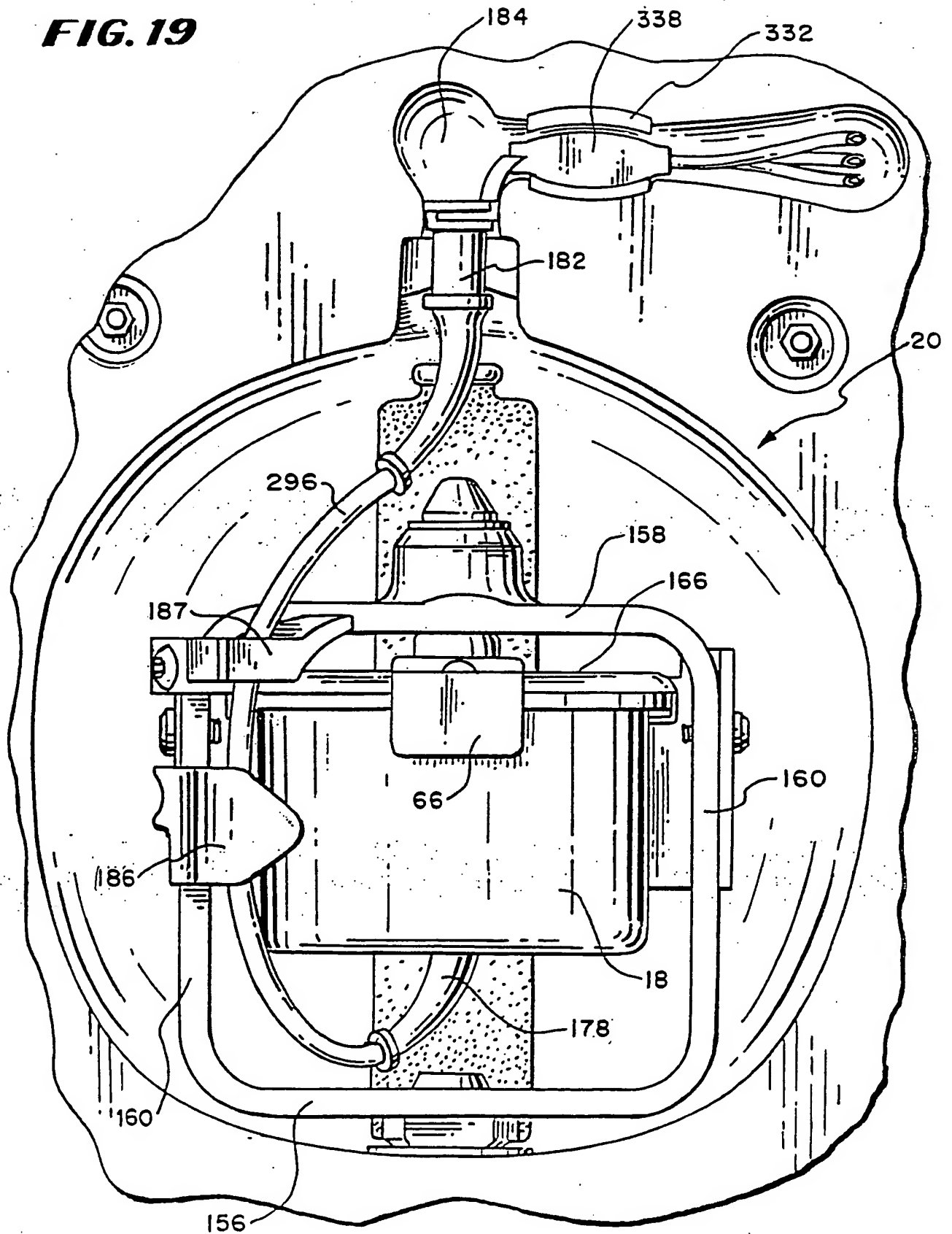
**FIG. 16**

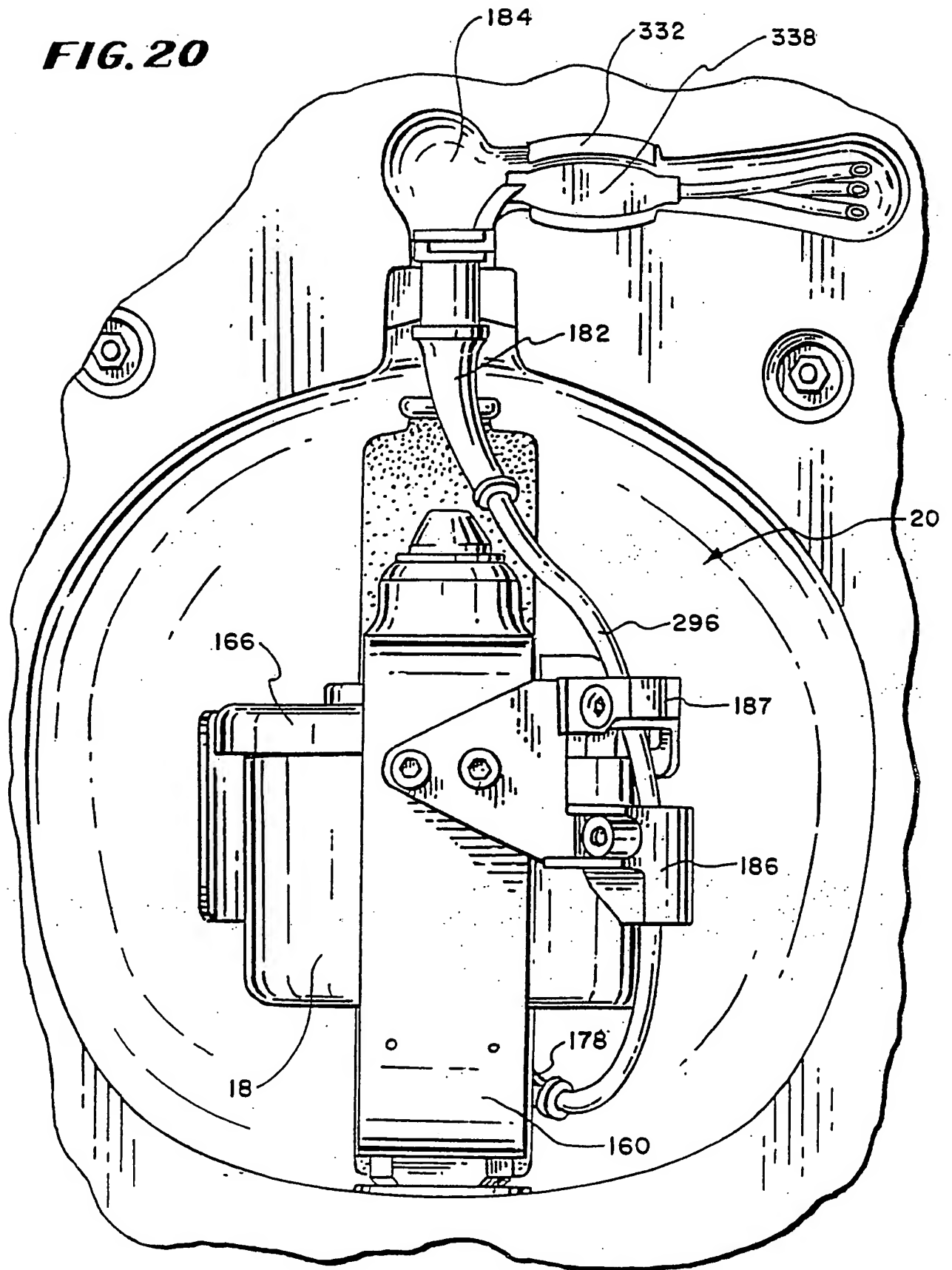


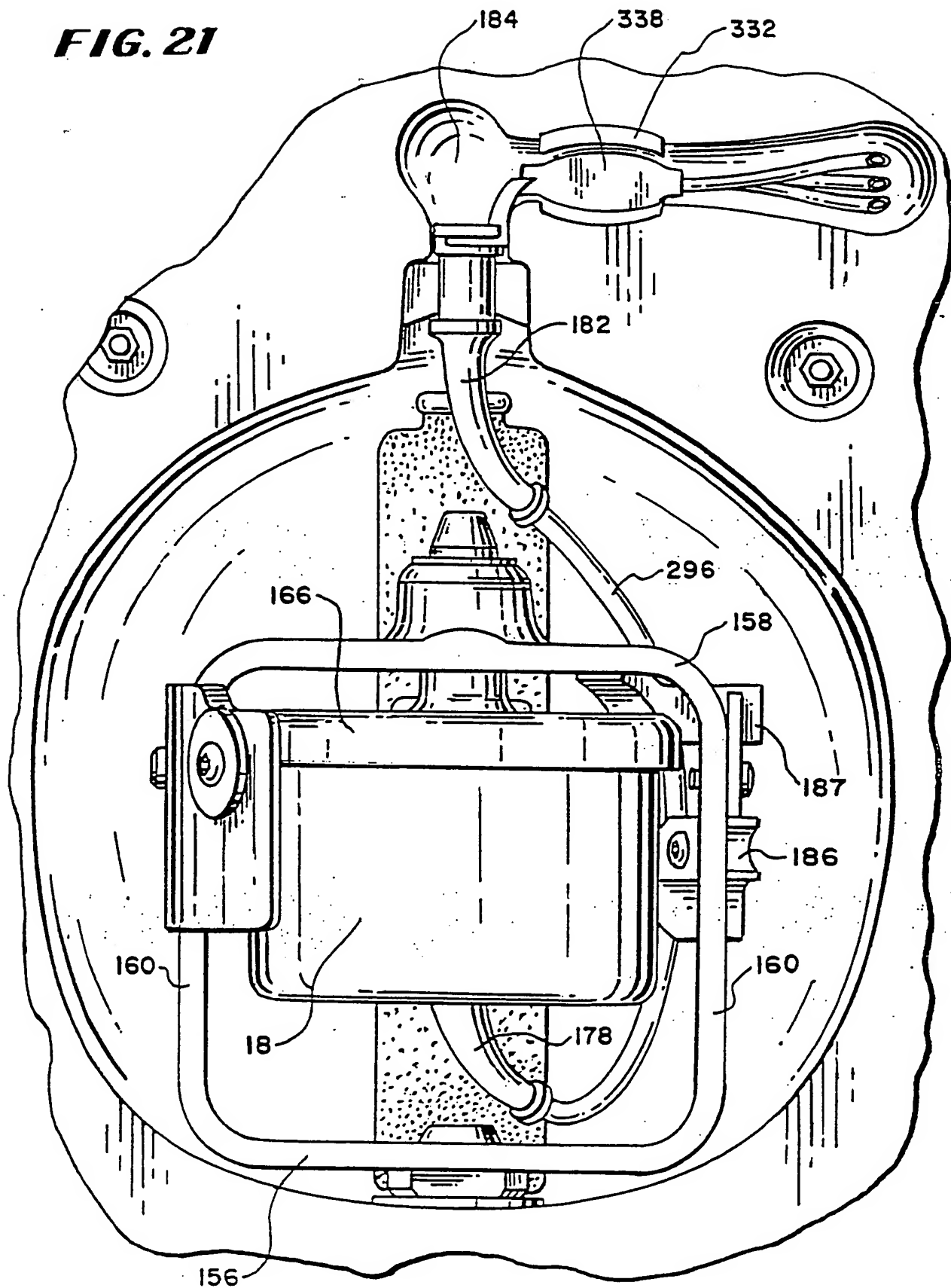
**FIG. 17**

**FIG. 18**

**FIG. 19**



**FIG. 20**

**FIG. 21**

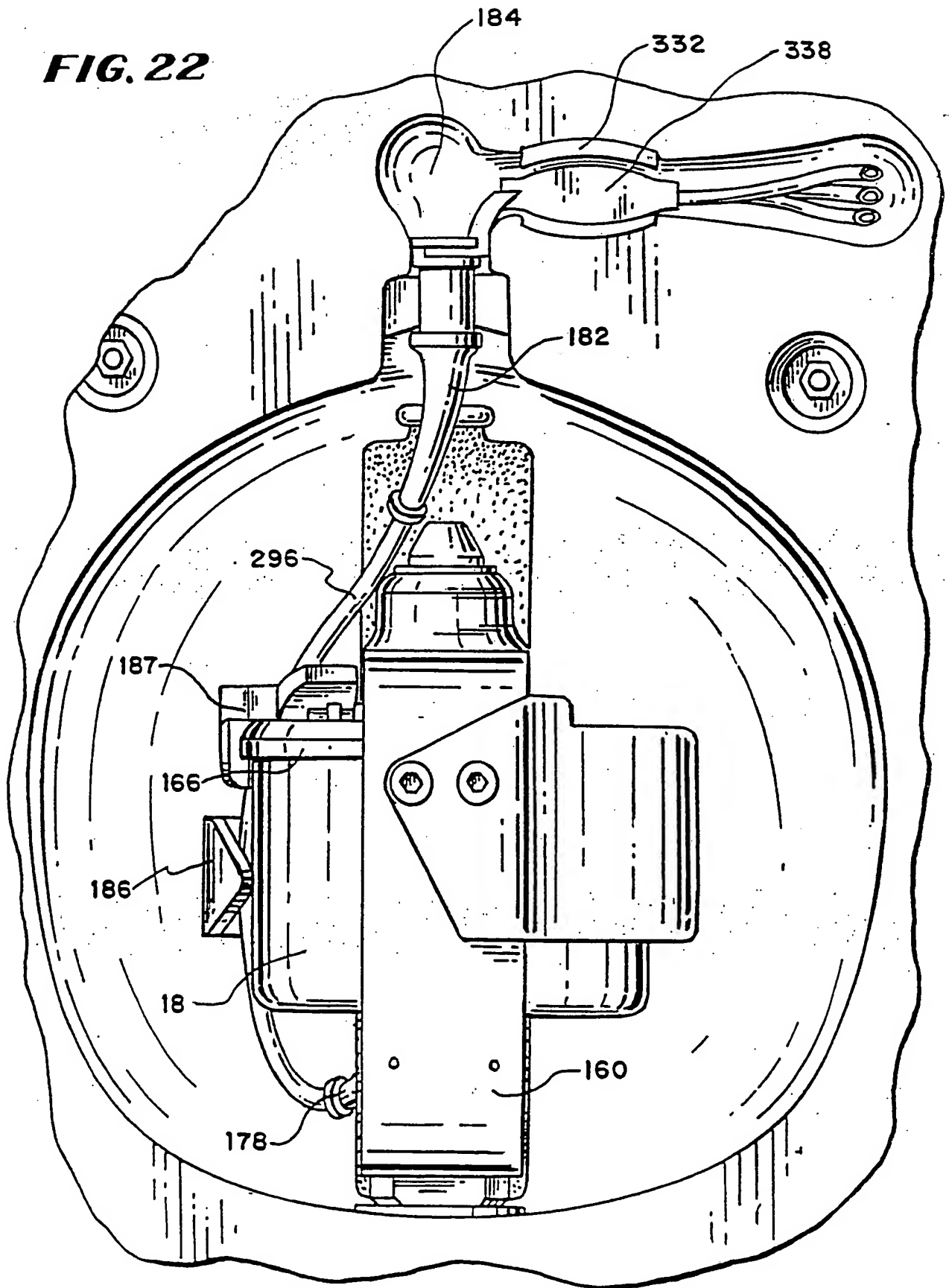
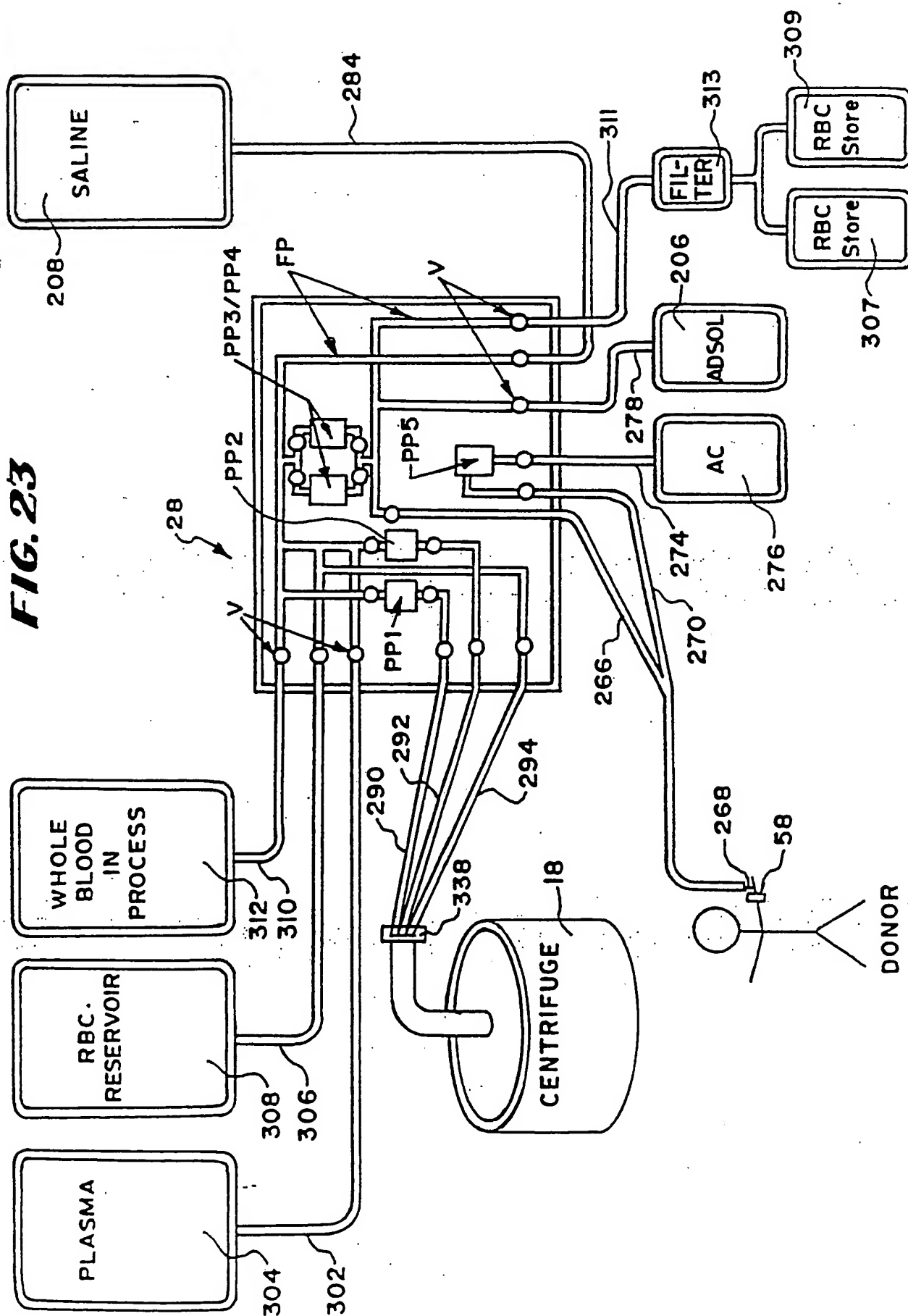
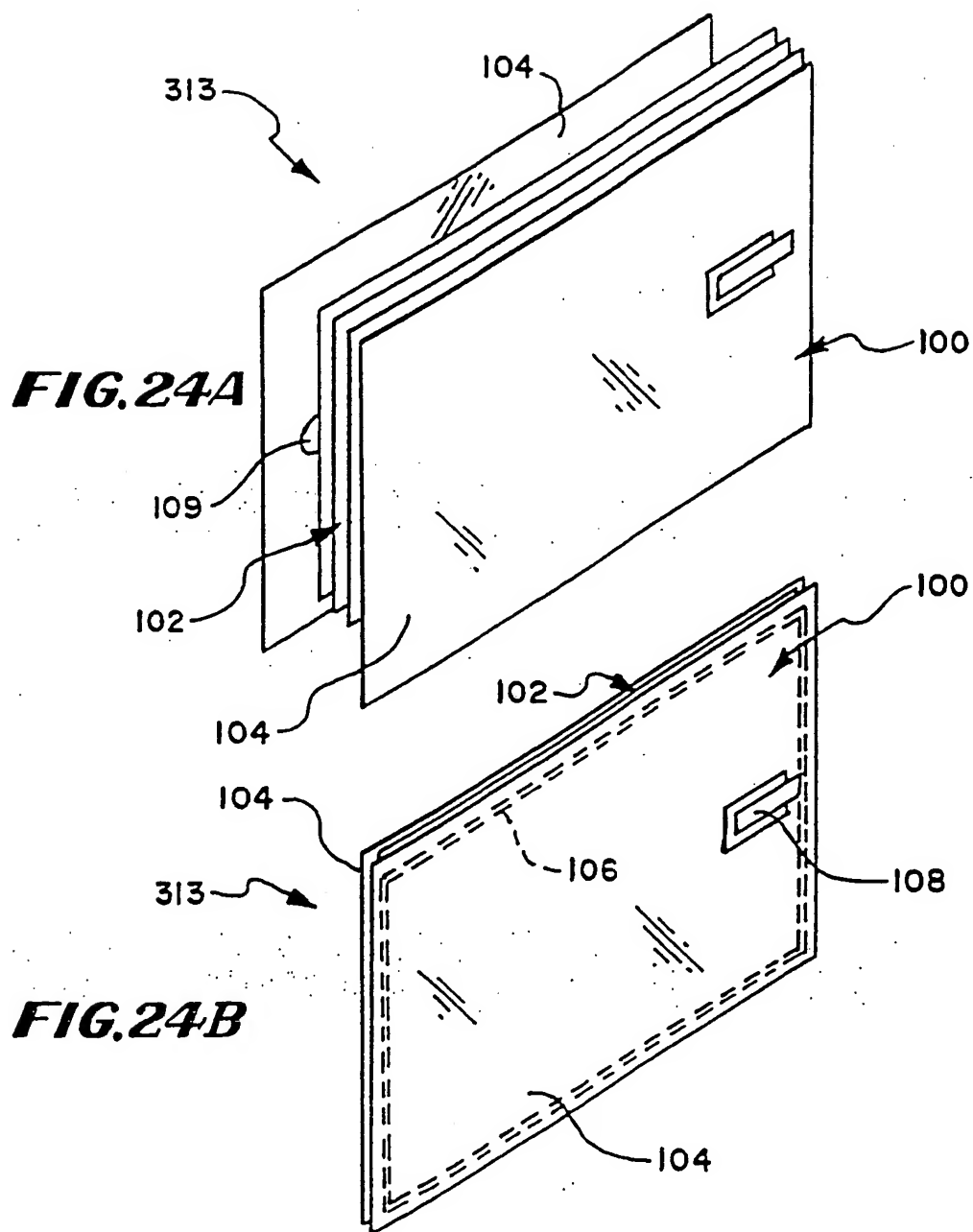
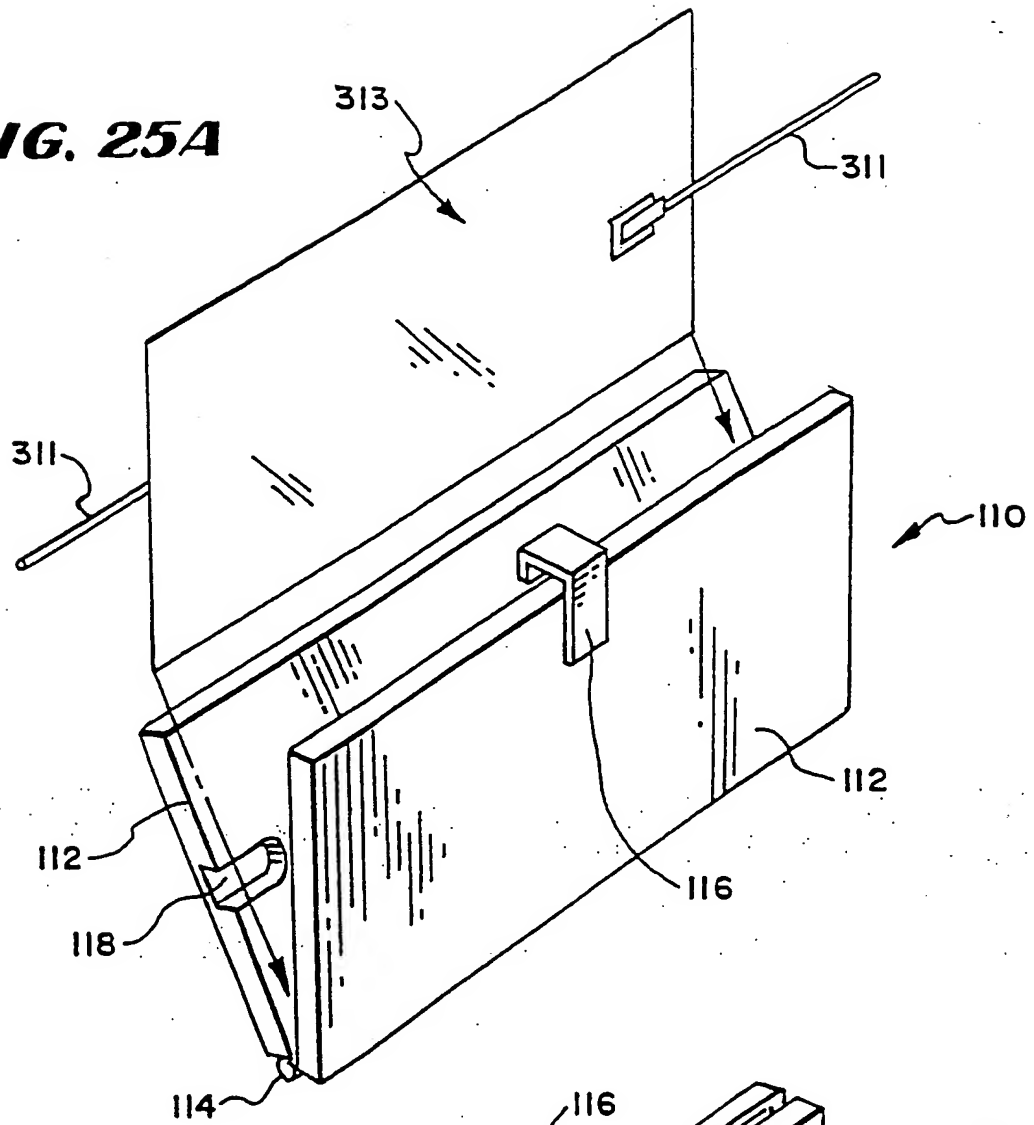
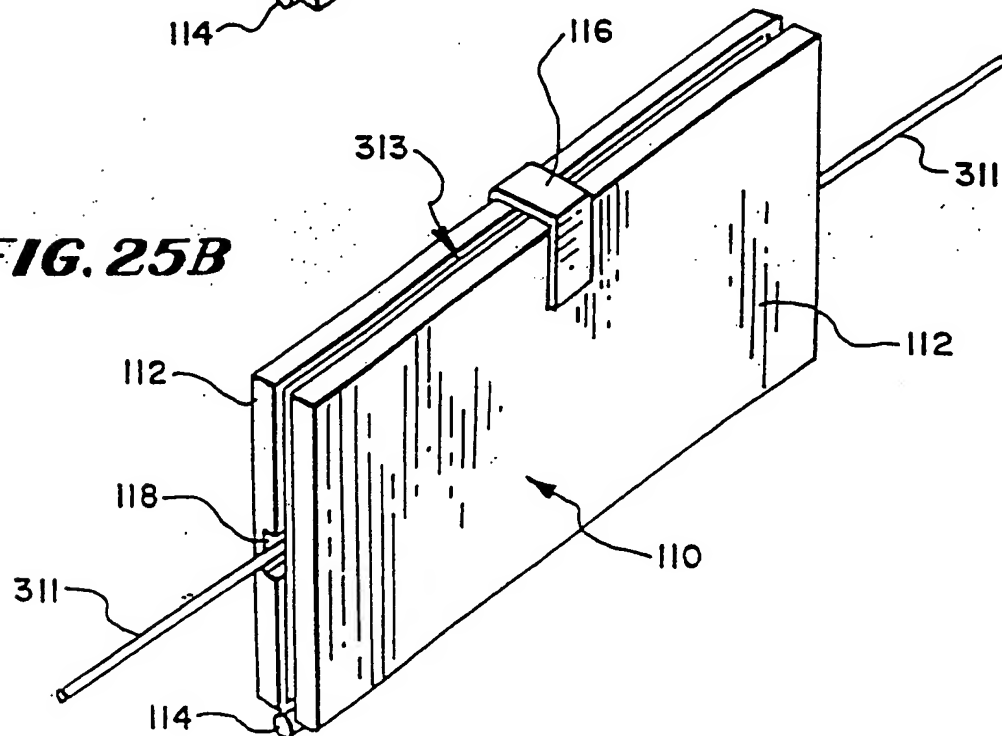
**FIG. 22**

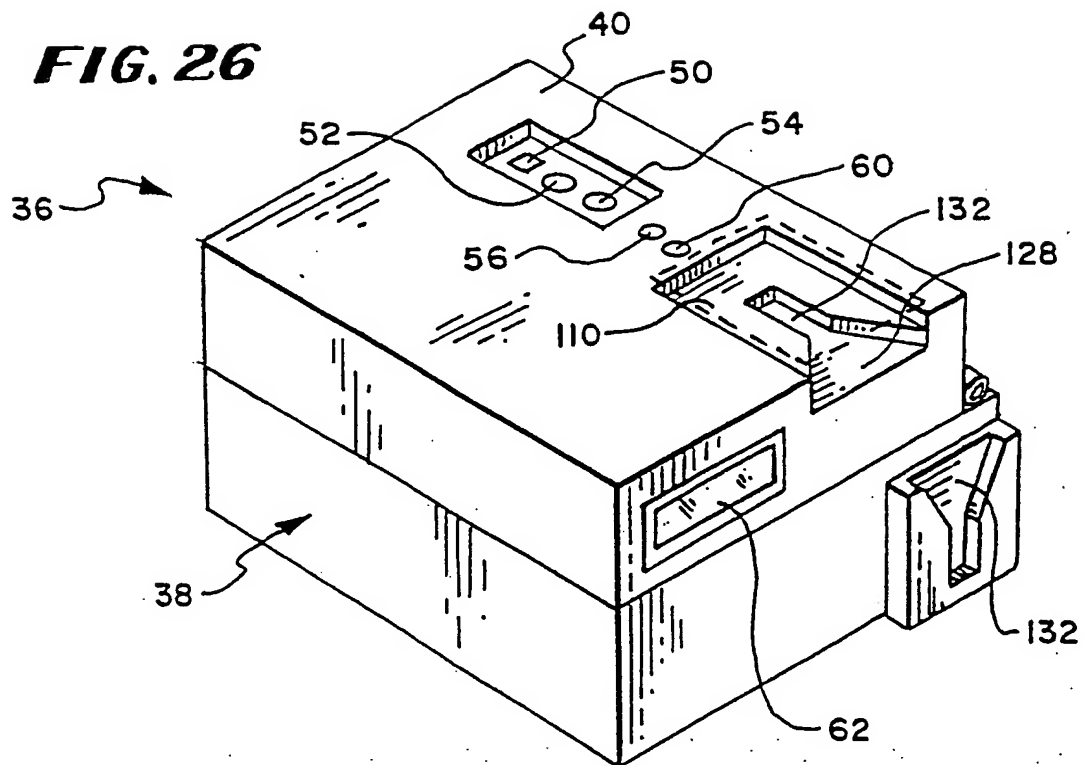


FIG. 23

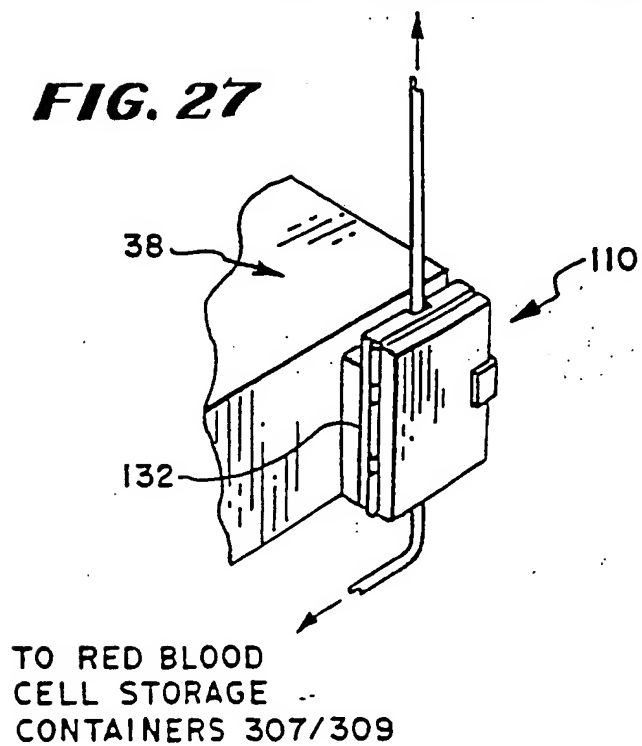
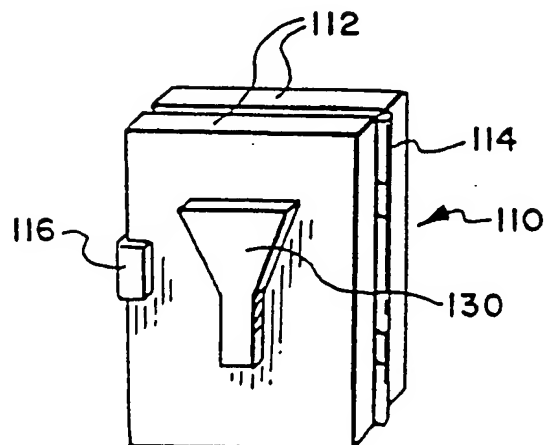


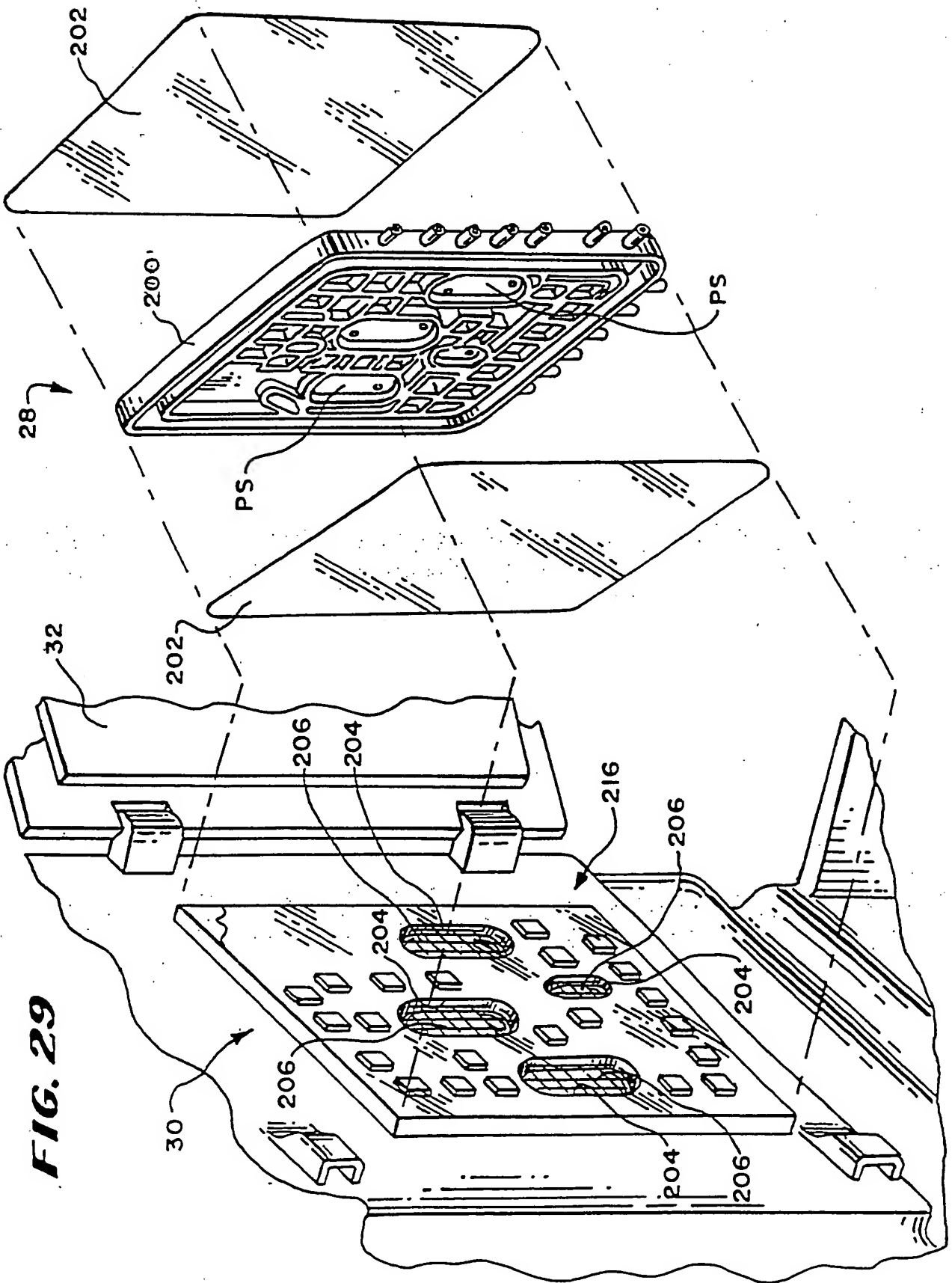


**FIG. 25A****FIG. 25B**

**FIG. 26**

FROM RED BLOOD  
CELL RESERVOIR 308

**FIG. 27****FIG. 28**



Customer No.: 26308

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Please amend the application prior to the first office action as follows:

### AMENDMENT TO THE CLAIMS

1 (Original). A blood processing system comprising

a blood processing set including a source of blood cells, and a blood component collection flow channel coupled to the source of blood cells including a blood cell storage container and an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container, the in-line filter including a fibrous filter medium, first and second flexible housings, a unitary, continuous peripheral seal formed by application of pressure and radio-frequency heating in a single process to join the first and second flexible housings to each other, as well as join the fibrous filtration medium to the first and second flexible housings, and

a pump station adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter.

2 (Original). A blood processing system according to claim 1

further including a fixture to restrain expansion of the first and second filter housings as a result of pressure applied during operation of the pump station.

3 (Original). A blood processing system according to claim 2

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

4 (Original). A blood processing system according to claim 1

wherein the source of blood cells includes a donor flow channel including a blood separation device to separate blood cells from donor whole blood.

5 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the controller includes a function to derive a value reflecting volume of blood cells present in the blood cell storage container after passage through the filter as a percentage of volume of blood cells conveyed to the filter.

6 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the pump station includes a fluid pressure actuated pump and an actuator to apply fluid pressure to the pump.

7 (Original). A system according to claim 1 or 2 or 3 or 4

wherein the blood cells comprise red blood cells.

8 (Original). A method of processing blood comprising using the blood processing system as defined in claim 1 or 2 or 3 or 4.

9 (New). In a method of filtering a liquid using a filter comprising a flexible housing having an inlet port and outlet port for the liquid and a sheet-like filter element for removing undesired components from the liquid, with the inlet port being separated from the outlet port by the filter element, a method characterized by maintaining the pressure at the outlet side of the filter at a positive pressure above atmospheric pressure by controlling a feed rate per unit time of a feed pump installed in an upstream flow channel of the filter.

10 (New). The method according to claim 9, wherein the filter does not comprise a spacer for securing a flow channel at the outlet side of the filter.

11 (New). The method according to claim 9 or claim 10, wherein the filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet side and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

12 (New). The method according to claim 9, wherein the liquid to be filtered is blood.

13 (New). The method according to claim 10, wherein the liquid to be filtered is blood.

14 (New). The method according to claim 11, wherein the liquid to be filtered is blood.

15 (New). The method according to claim 12, wherein the filter is used for removal of leukocytes.

16 (New). The method according to claim 13, wherein the filter is used for removal of leukocytes.

17 (New). The method according to claim 14, wherein the filter is used for removal of leukocytes.

18 (New). In a filtering system for a liquid comprising a filter comprising a flexible housing having an inlet port and outlet port for the liquid, a sheet-like filter element for removing undesired components from the liquid, with the liquid inlet port and the outlet port separated from each other by the filter element, an upstream side flow channel connected to the filter inlet port, a filtered liquid recovery bag, a downstream side flow channel connecting the filter outlet port with the recovery bag, and a feed pump installed in the upstream side flow channel, a filtering system wherein the feed



rate per unit time of a feed pump installed in an upstream flow channel of the filter can be controlled so that the pressure at the outlet side of the filter is maintained at positive pressure above atmospheric pressure.

19 (New). The system according to claim 18, comprising the filter without a spacer for securing a flow channel at the outlet side of the filter.

20 (New). The system according to a claim 18 or claim 19, wherein a filter of which the outlet side flexible housing has not been processed to provide irregularity as a spacer for securing a flow channel at the filter outlet port and/or a filter in which a tube is not inserted between the outlet side flexible housing and the sheet-like filter as a spacer for securing a flow channel at the filter outlet side are/is used.

21 (New). The system according to claim 18, wherein the liquid to be filtered is blood.

22 (New). The system according to claim 19, wherein the liquid to be filtered is blood.

23 (New). The system according to claim 20, wherein the liquid to be filtered is blood.

24 (New). The system according to claim 21, wherein the filter is used for removal of leukocytes.

25 (New). The system according to claim 22, wherein the filter is used for removal of leukocytes.

26 (New). The system according to claim 23, wherein the filter is used for removal of leukocytes.

27 (New). A liquid filtering method using the system according to claim 18.

28 (New). A liquid filtering method using the system according to claim 19.

29 (New). A liquid filtering method using the system according to claim 20.

30 (New). A liquid filtering method using the system according to claim 21.

31 (New). A liquid filtering method using the system according to claim 22.

32 (New). A liquid filtering method using the system according to claim 23.

33 (New). A liquid filtering method using the system according to claim 24.

34 (New). A liquid filtering method using the system according to claim 25.

35 (New). A liquid filtering method using the system according to claim 26.

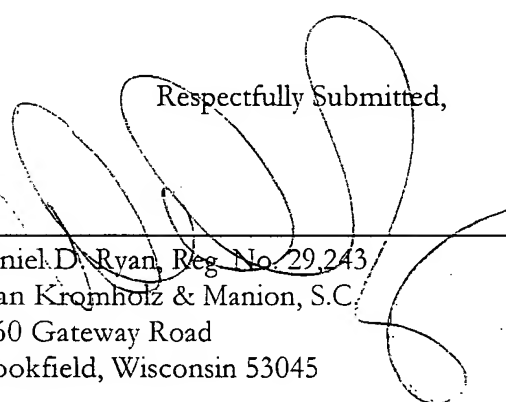
### REMARKS

New claims 9 to 35 have been added. The new claims are patterned after claims 11 to 16 and 29 to 35 of co-pending United States Patent Application Serial No. 10/474,805, filed April 2, 2002 (Foreign Priority: April 13, 2001), entitled "Liquid Filtering Method and Filtering System." With respect to these new claims 9 to 35, applicant concurrently files a document Suggesting an Interference Pursuant to 37 C.F.R. § 41.202(a), with companion Declarations.

Applicant notes that the instant application is a continuation of United States Patent Application Serial No. 09/976,833, filed October 13, 2001, now United States Patent No. 6,709,412.

A request for Correction of Inventorship also accompanies this Amendment, by the addition of co-inventors and Tom Westberg and Rohit Vishnoi. The submission of new claims 9 to 35 necessitated this request. The co-inventors of the subject matter defined in new claims 9 to 35 are Mark Vandlik, Tom Westberg, and Rohit Vishnoi.

Respectfully Submitted,

By   
Daniel D. Ryan, Reg. No. 29,243  
Ryan Kromholz & Manion, S.C.  
3360 Gateway Road  
Brookfield, Wisconsin 53045

Gary W. McFarron, Reg. No. 27,357  
David Lesht, Reg. No. 30,472  
Cook, Alex, McFarron, Manzo, Cummings & Mehler  
200 W. Adams St., Suite 2850  
Chicago, Illinois 60606

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
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(262) 783 - 1300  
Customer No.: 26308

Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**Request for Correction of Inventorship**

**Pursuant to 37 C.F.R. §1.48(c)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant hereby requests, pursuant to 37 C.F.R. §1.48(c), correction of inventorship in the above identified case by the addition of joint inventors Tom Westberg and Rohit Vishnoi. The addition of inventors is necessitated by amendment of the claims to add subject matter not present in the claims at the time this case was filed.

As required by 37 C.F.R. §1.48(b), accompanying this Request are:

1. Statements from added inventors Tom Westberg and Rohit Vishnoi that their addition is necessitated by amendment of the claims and that the inventorship error occurred without any deceptive intent on his part (TAB 1).
2. An assignment, executed by the added inventors Tom Westberg and Rohit Vishnoi, with a Request for Recordation (TAB 2). The assignment of the originally inventors Mark R. Vandlik, Michael J. Kast, and Kelly B. Smith has been previously recorded in the parent application (Serial Number 09/976833, now US 6,709,412) in Reel/Frame 012582/0905.
3. The written consent of the assignee to the correction (TAB 3).
4. A Declaration by the actual inventors as required by 37 C.F.R. §1.63 (TAB 4). Originally-named inventor (and assignor) Kelly B. Smith cannot at the present time be reached for signature (she has moved and her exact whereabouts are not known), and a Petition under 37 C.F.R. § 1.183

(TAB 5) requesting a waiver of the requirement of 37 C.F.R. § 1.64 when as here, assignee has consented to the correction (see MPEP 201.03 (B)), accompanies this Petition for Correction,.

5. The processing fee as set forth in 37 C.F.R. §1.17(i).

A check payable in an amount to cover the requisite processing fee for this Request to Change Inventorship and Request for Recordation of Assignment is attached. You are authorized to charge any excess fees, or to credit overpayments, to Deposit Account No. 06-2360. A copy of this Request (without attachments) is attached for this purpose.

Approval of this Request is respectfully solicited.

Respectfully Submitted,

By

Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308

Customer No.: 26308

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

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Filed: January 26, 2004

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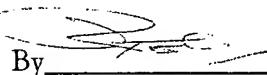
Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**STATEMENT OF ROHIT VISHNOI  
UNDER 37 C.F.R. 1.48(c) (2)**

I, Rohit Vishnoi, do understand that a petition has been made to change the inventorship in this patent by adding me as a joint inventor. I also understand that the addition was necessitated by amendment of the claims. The inventorship error occurred without any deceptive intention on my part.

I know that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the patent issued hereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Dated 7/22/04

By   
Rohit Vishnoi

Customer No.: 26308

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

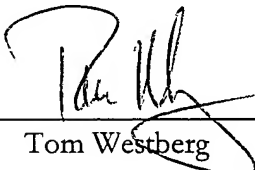
Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**STATEMENT OF TOM WESTBERG  
UNDER 37 C.F.R. 1.48(c) (2)**

I, Tom Westberg, do understand that a petition has been made to change the inventorship in this patent by adding me as a joint inventor. I also understand that the addition was necessitated by amendment of the claims. The inventorship error occurred without any deceptive intention on my part.

I know that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the patent issued hereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Dated 7/25/05

By   
Tom Westberg

RYAN KROMHOLZ & MANION, S.C.

17287

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## RECORDATION FORM COVER SHEET PATENTS ONLY

To the Director of the U.S. Patent and Trademark Office: Please record the attached documents or the new address(es) below.

**1. Name of conveying party(ies)/Execution Date(s):**

Tom Westberg  
Rohit Vishnoi

Execution Date(s) 7/25/2005 and 7/28/2005

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

**2. Name and address of receiving party(ies)**

Name: Baxter International Inc.

Internal Address: \_\_\_\_\_

Street Address: One Baxter Parkway

City: Deerfield

State: Illinois

Country: US

Zip: 60015

Additional name(s) & address(es) attached? ☐ Yes ☒ No

**3. Nature of conveyance:**

- ☒ Assignment ☐ Merger  
☐ Security Agreement ☐ Change of Name  
☐ Government Interest Assignment  
☐ Executive Order 9424, Confirmatory License  
☐ Other \_\_\_\_\_

**4. Application or patent number(s):**

☐ This document is being filed together with a new application.

A. Patent Application No.(s)

10/765,498

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

**5. Name and address to whom correspondence concerning document should be mailed:**

Name: Daniel D. Ryan

Internal Address: Ryan Kromholz & Manion, S.C.

Street Address: P.O. Box 26618

City: Milwaukee

State: Wisconsin

Zip: 53226

Phone Number: 262 783 1300

Fax Number: 262 783 1211

Email Address: \_\_\_\_\_

**6. Total number of applications and patents involved:**

**7. Total fee (37 CFR 1.21(h) & 3.41) \$ 40.00**

- ☐ Authorized to be charged by credit card  
☐ Authorized to be charged to deposit account  
☒ Enclosed  
☐ None required (government interest not affecting title)

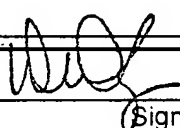
**8. Payment Information**

a. Credit Card Last 4 Numbers \_\_\_\_\_  
Expiration Date \_\_\_\_\_

b. Deposit Account Number 06-2360

Authorized User Name Daniel D. Ryan

**9. Signature:**



Signature

4 August 2005

Date

Daniel D. Ryan

Name of Person Signing

Total number of pages including cover sheet, attachments, and documents:



Serial No. (1) 10/765,498Filed (1) 01/26/2004

In consideration of ONE DOLLAR and other good and valuable considerations, the receipt and sufficiency whereof are hereby acknowledged, we hereby assign to BAXTER INTERNATIONAL INC. (hereinafter referred to as "assignee"), a corporation of Delaware, having a principal place of business at DEERFIELD, ILLINOIS, its successors, legal representatives and assigns, the entire right, title and interest throughout the world in our invention or improvements in

**(2) Blood Processing Systems and Methods that Employ an  
In-Line Leukofilter Mounted in a Restraining Fixture**

and in the application for Letters Patent of the United States therefor, executed by each of us individually on the date(s) indicated below and any and all other United States applications and applications in any and all countries which we may file, either solely or jointly with others, on said invention or improvements, and in any and all Letters Patent of the United States or of any other country which may be obtained on any of the said applications, and in any reissue or extension thereof.

We hereby authorize and request the Commissioner of Patents to issue said Letters Patent to said BAXTER INTERNATIONAL INC.

We hereby authorize and request the attorneys of record in said application to insert in this assignment the date and serial number of said application when officially known.

We warrant ourselves to be the owners of the interest herein assigned and to have the right to make this assignment; and further warrant that there are no outstanding prior assignments, licenses, or other rights in the interest herein assigned.

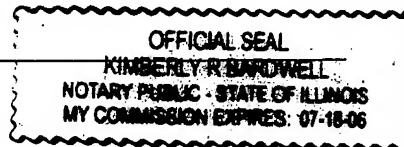
For said considerations we hereby agree, upon the request and at the expense of said assignee, its successors, legal representatives and assigns, to execute any and all divisional, continuation, and renewal applications for said invention or improvements, and any necessary oath or supplemental oath or affidavit relating thereto, and any application for the reissue or extension of any Letters Patent that may be granted upon said application that said assignee, its successors, legal representatives and assigns may deem necessary or expedient, and for the said considerations we further agree, upon the request of said assignee, its successors, legal representatives and assigns, in the event of said application or any division thereof, or Letters Patent issued thereon, or any reissue or application for the reissue thereof becoming involved in interference, to cooperate to the best of our ability with said assignee, its successors, legal representatives and assigns in the matters of preparing and executing the preliminary statement and giving and producing evidence in support thereof. We further agree to perform, upon such request, any and all affirmative acts to obtain Letters Patent, and vest all rights therein hereby conveyed in the said assignee, its successors, legal representatives and assigns whereby said Letters Patent will be held and enjoyed by the said assignee, its successors, legal representatives and assigns to the end of the term for which said Letters Patent may be granted as fully and entirely as the same would have been held and enjoyed by us if this assignment and sale had not been made, and for the said considerations we hereby also assign to said assignee, its successors, legal representatives and assigns the entire right, title and interest in said invention or improvements for any and all foreign countries and the right of priority for patent and utility model applications in all countries arising under any applicable international convention for the protection of industrial property and/or any internal priority legislation of such countries, and we further agree upon the request of said assignee, its successors, legal representatives and assigns to execute any and all documents that shall be required to be executed in connection with any and all applications for foreign Letters Patent therefor, including the prosecution thereof, and to execute any and all documents necessary to invest title in said foreign applications and patents in said assignee.

WITNESS our hand and seal

Date 7/25/05 Signature *Tom Westberg*(3) Typed Name: Tom Westberg

(4) State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by Tom Westberg  
Inventor\_\_\_\_\_  
Notary PublicDate 7/28/05 Signature *Rohit Vishnoi*(3) Typed Name: Rohit Vishnoi(4) State of Illinois, County of StateSigned before me on this 28 day of July, 2005by Rohit Vishnoi  
Inventor\_\_\_\_\_  
Notary Public

Date \_\_\_\_\_ Signature \_\_\_\_\_

(3) Typed Name: \_\_\_\_\_

(4) State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by \_\_\_\_\_  
Inventor

Date \_\_\_\_\_ Signature \_\_\_\_\_

(3) Typed Name: \_\_\_\_\_

(4) State of \_\_\_\_\_, County of \_\_\_\_\_

Signed before me on this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_

by \_\_\_\_\_  
Inventor



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## Assignments on the Web &gt; Patent Query

## Patent Assignment Abstract of Title

**NOTE: Results display only for issued patents and published applications.  
For pending or abandoned applications please consult USPTO staff.**

## Total Assignments: 1

Patent #: [6709412](#)

Issue Dt: 03/23/2004 Application #: 09976833 Filing Dt: 10/13/2001

Publication #: [US20020090319](#) Pub Dt: 07/11/2002

Inventors: Mark R. Vandlik, Michael J. Kast, Kelly B. Smith

Title: BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN IN-LINE LEUKOFILTER  
MOUNTED IN A RESTRAINING FIXTURE

## Assignment: 1

Reel/Frame: [012582/0905](#)

Recorded: 02/12/2002

Pages: 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: [VANDLIK, MARK R.](#)

Exec Dt: 01/22/2002

[KAST, MICHAEL J.](#)

Exec Dt: 01/21/2002

[SMITH, KELLY B.](#)

Exec Dt: 01/21/2002

Assignee: [BAXTER INTERNATIONAL INC](#)ONE BAXTER PARKWAY(2-2E)  
DEERFIELD, ILLINOIS 60015

Correspondent: RYAN KROMHOLZ &amp; MANION, S.C.

DANIEL D. RYAN  
P.O. BOX 26618  
MILWAUKEE, WI 53226

Search Results as of: 08/02/2005 11:11 AM

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Customer No.: 26308

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

CONSENT OF ASSIGNEE  
TO CHANGE OF INVENTORSHIP  
PURSUANT TO 37 C.F.R. §1.48(c)

Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

Baxter International Inc., One Baxter Parkway, Deerfield, Illinois 60015, the owner of 100% interest in this U.S. Patent Application by virtue of assignment, hereby assents to the correction of inventorship filed herewith, namely adding Tom Westberg and Rohit Vishnoi as co-inventors.

I state that I am authorized to act on behalf of the assignee.

In accordance with 37 C.F.R. 3.73, the assignee hereby certifies that the evidentiary documents with respect to ownership have been reviewed and that, to the best of the assignee's knowledge and belief, title is in the assignee seeking to take this action.

Dated

August 3, 2005

By

David P. Scharf D.P.S.

Typed Name David P. Scharf

Assistant Corporate Secretary  
Title and Associate General Counsel

**COMBINED DECLARATION AND POWER OF ATTORNEY  
(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,  
CONTINUATION OR CIP)**

As a below named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type: *(check one applicable item below)*

- ☒ original  
☐ supplemental

Type of Application: *(check one applicable item below)*

- ☐ original  
☐ design

NOTE: *If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.*

- ☐ national stage of PCT

NOTE: *If one of the following items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.*

- ☐ divisional  
☒ continuation  
☐ continuation-in-part (CIP)

**INVENTORSHIP IDENTIFICATION**

WARNING: *If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**TITLE OF INVENTION**

BLOOD PROCESSING SYSTEMS AND METHODS THAT EMPLOY AN  
IN-LINE LEUKOFILTER MOUNTED IN A RESTRAINING FIXTURE

**SPECIFICATION IDENTIFICATION**

the specification of which: *(complete (a), (b) or (c))*

- (a) ☐ is attached hereto.  
(b) ☒ was filed on 26 January 2004 as ☐ Serial No. 10/765,498  
or ☐ Express Mail No., as Serial No. not yet known \_\_\_\_\_  
and was amended on \_\_\_\_\_ (if applicable).

NOTE: *Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.*

- (c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_  
filed on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_  
(if any).

# ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

- ☐ In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

## PRIORITY CLAIM (35 U.S.C. § 119)

- A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

- (d) ☒ no such applications have been filed.  
(e) ☐ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>

- B. CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) (35 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

Provisional Application No.	Filing Date
<hr/>	<hr/>
<hr/>	<hr/>
<hr/>	<hr/>

## CLAIM FOR BENEFIT OF EARLIER US and/or PCT APPLICATION(S) UNDER 35 U.S.C. § 120

- ☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR US PRIORITY CLAIM

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS  
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

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NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. S 120.

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(List name and registration number)*

Daniel D. Ryan (29,243)  
John M. Manion (38,957)  
Laura A. Dable (46,436)  
Patricia A. Limbach (50,295)  
Thomas J. Krumenacher (56,736)

Bradford R.L. Price (29,101)  
Joseph A. Kromholz (34,204)  
Daniel R. Johnson (46,204)  
Patrick J. Fleis (55,185)  
Melissa S. Hockersmith (56,960)

*(check the following item, if applicable)*

☐ Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

---

SEND CORRESPONDENCE TO

Bradford R.L. Price, Esquire  
BAXTER HEALTHCARE CORPORATION  
Senior Counsel  
One Baxter Parkway (DF3-2E)  
Deerfield, IL 60015

DIRECT TELEPHONE CALLS TO:  
(Name and telephone number)

Bradford R.L. Price  
(847) 948-4483

---

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

Full name of sole or first inventor

MARK (GIVEN NAME) R (MIDDLE INITIAL OR NAME) VANDLIK (FAMILY (OR LAST NAME))  
 Inventor's signature *Mark Vandlik*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS HAWTHORN WOODS, IL  
 Post Office Address 7742 GENEVA DRIVE 47 OLD LAKE ROAD  
GURNEE, ILLINOIS 60031 HAWTHORN WOODS, IL 60047 *7/27/05*

Full name of second joint inventor, if any

MICHAEL (GIVEN NAME) J (MIDDLE INITIAL OR NAME) KAST (FAMILY (OR LAST NAME))  
 Inventor's signature *Michael J Kast*  
 Date 7/25/05 Country of Citizenship US  
 Residence (City, State/Country) EVANSTON, ILLINOIS  
 Post Office Address 1152 ASHLAND AVENUE  
EVANSTON, ILLINOIS 60202

Full name of third joint inventor, if any

KELLY (GIVEN NAME) B (MIDDLE INITIAL OR NAME) SMITH (FAMILY (OR LAST NAME))  
 Inventor's signature \_\_\_\_\_  
 Date \_\_\_\_\_ Country of Citizenship US  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 506 CRYSTAL PLACE  
GURNEE, ILLINOIS 60031

Full name of fourth joint inventor, if any

TOM (GIVEN NAME) (MIDDLE INITIAL OR NAME) WESTBERG (FAMILY (OR LAST NAME))  
 Inventor's signature *Tom Westberg*  
 Date 7/25/2005 Country of Citizenship FI  
 Residence (City, State/Country) GURNEE, ILLINOIS  
 Post Office Address 17820 POND RIDGE CIRCLE  
GURNEE, ILLINOIS 60031

Full name of fifth joint inventor, if any

ROHIT (GIVEN NAME) (MIDDLE INITIAL OR NAME) VISHNOI (FAMILY (OR LAST NAME))  
 Inventor's signature *Rohit Vishnoi*  
 Date 7/25/2005 Country of Citizenship US  
 Residence (City, State/Country) DEERFIELD, ILLINOIS  
 Post Office Address 235 WILSON AVENUE  
DEERFIELD, ILLINOIS 60015

**ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR US PRIORITY CLAIM**

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120**

I hereby claim the benefit under Title 35, United States Code, S 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, S 112, I acknowledge the duty to disclose information that is material to the examination of this application, namely, information where there is substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120:**

Status  
(CHECK ONE)

U.S. APPLICATIONS	U.S. FILING DATE	Patented	Pending	Abandoned
1. 09/976,833	10/13/2001	X		
2. 09/389,504	09/03/1999			X
3. _____	_____			

**PCT APPLICATIONS DESIGNATING THE U.S.**

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NOS. ASSIGNED (if any)
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____

**35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS**

**DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY APPLICATION  
CLAIMED UNDER 35 USC 119**

	Country	Application No.	Date of filing (day, month, year)	Date of issue (day, month, year)
1.	_____	_____	_____	_____
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____



CHECK PROPER BOX 3) FOR ANY OF THE FOLLOWING ADD PAGE(S) WHICH  
FORM A PART OF THIS DECLARATION

☐ Signature for sixth and subsequent joint inventors.

\* \* \*

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor.

\* \* \*

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47.

\* \* \*

☒ Added page to combined declaration and power of attorney for US Priority Claim

\* \* \*

☐ Authorization of attorney(s) to accept and follow instructions from representative

\* \* \*

*(If no further pages form a part of this declaration then end this declaration with this page and check the following item:)*

☐ This declaration ends with this page

RYAN KROMHOLZ & MANION, S.C.

17289

		CHECK			
DATE	DESCRIPTION	INVOICE #	AMOUNT	DEDUCTION	NET AMOUNT
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RYAN KROMHOLZ & MANION, S.C.

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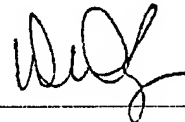
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Commissioner for Patents



⑈017289⑈ ⑆075900575⑆ 0014 033 548⑈

Customer No.: 26308

Patent

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vandlik et al

Attorney Docket No.: F-5489 CIP2 Con

Serial No.: 10/765,498

Examiner: P. Bianco

Filed: January 26, 2004

Group Art Unit: 3762

Title: Blood Processing Systems and Methods that Employ an In-Line Flexible Leukofilter

**Petition Pursuant to 37 C.F.R. §1.183**

**Requesting Waiver of Requirement of 37 C.F.R. § 1.64**

**That an Original Inventor (Kelly B. Smith) Execute New Oath or Declaration**

**When New Inventors Are Added With Assignee's Consent**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant has requested, pursuant to 37 C.F.R. §1.48(c), a correction of inventorship in the above identified case by the addition of joint inventors Tom Westberg and Rohit Vishnoi. The addition of inventors is necessitated by amendment of the claims to add subject matter not present in the claims at the time this case was filed. Statements under 37 C.F.R. §1.48(c)(2); assignments; and a new Declaration have been executed by added inventors Tom Westberg and Rohit Vishnoi and have been submitted with the request. Original inventors Mark R. Vandlik and Michael Kast have also executed the new Declaration. However, original inventor Kelly B. Smith has not, as yet, been located to obtain her signature on the new Declaration. Active efforts are ongoing to locate her and ask her to join in on the execution of the new Declaration.

An assignment, executed by the original inventors Mark Vandlik, Michael Kast, and Kelly B. Smith has been previously recorded in the parent application (Serial Number 09/976833, now US 6,709,412) in Reel/Frame 012582/0905. The assignee Baxter International Inc. has consented to the correction of inventorship.

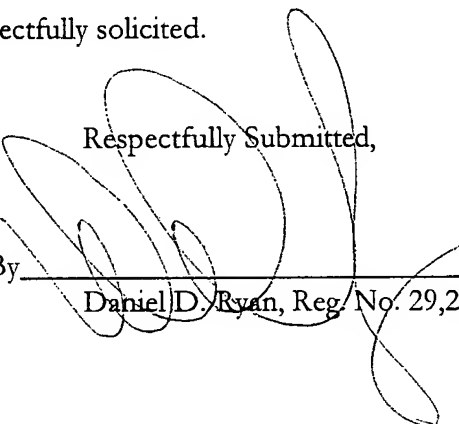
Under such circumstances, as directed by MPEP 201.03 (B), applicant submits this Petition under 37 C.F.R. § 1.183, requesting a waiver of the requirement of 37 C.F.R. § 1.64 that Kelly B. Smith sign the new Declaration, when as here, the assignee has consented to the correction to add new inventors.

The processing fee as set forth in 37 C.F.R. §1.17(i) accompanies this Petition. You are authorized to charge any excess fees, or to credit overpayments, to Deposit Account No. 06-2360. A copy of this Petition is attached for this purpose.

Approval of this Petition is respectfully solicited.

Respectfully Submitted,

By

  
Daniel D. Ryan, Reg. No. 29,243

RYAN KROMHOLZ & MANION, S.C.  
Post Office Box 26618  
Milwaukee, Wisconsin 53226  
(262) 783 - 1300  
Customer No.: 26308